EXHIBIT C

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC.,	Master File No.
PELVIC REPAIR SYSTEM PRODUCTS	2:12-MD-02327
LIABILITY LITIGATION	MDL 2327

THIS DOCUMENT RELATES TO CASE CONSOLIDATION:

Terreski Mullins, et al., v.

Ethicon, Inc., et al.

Case No. 2:12-CV-02952

DEPOSITION OF

VLADIMIR IAKOVLEV, M.D.

* * * *

HIGHLY CONFIDENTIAL PORTION

* * * *

September 11, 2015

9:00 a.m. - 5:05 p.m.

Deposition of VLADIMIR IAKOVLEV, M.D., a witness herein, called for examination by counsel for the Defense, in the above-mentioned matter, the witness having been affirmed, taken at the law offices of Siskinds LLP, 100 Lombard Street, Toronto, Ontario, commencing at 9:03 a.m. on Friday, September 11, 2015, and the proceedings taken down by Stenotype and transcribed by JUDITH M. CAPUTO, RPR, CSR, CRR.

A P P E A R A N C E S:

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I N D E X

WITNESS: VLADIMIR IAKOVLEV

INDEX OF EXHIBITS

-- NOTE: Exhibit 4 was retained by Mr. Thomas.

EXHIBIT NO. 1: Expert Report of Dr. Vladimir Iakovlev in the Mullins consolidated cases.
EXHIBIT NO. 2: Supplemental Expert Report of Dr. Vladimir Iakovlev in the Mullins consolidated cases.
EXHIBIT NO. 3: Notice of Deposition of Dr. Vladimir Iakovlev.
EXHIBIT NO. 4: Thumb drive.

Whereupon,
VLADIMIR IAKOVLEV, M.D.,
called for examination by counsel for Defendant and having been affirmed by me, was examined and testified as follows:

DIRECT EXAMINATION BY MR. THOMAS:

Q. Good morning, Doctor.

We've met before. My name is David Thomas. I'm going to ask you a number of questions about your expert witness opinion in the Mullins case pending in the MDL in West Virginia; fair enough?

A. Yes.

Q. I'm going to hand you what I've marked as Exhibits 1 and 2 and ask you if Exhibit

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Nos. 1 and 2 are the expert reports that you prepared in the Mullins case.

A. Yes, that's correct. This one is on the left, the thicker one, is a combination of several patients and this one on the right, Exhibit No. 2, is a supplemental set of figures specifically from the specimen of Ms. Mullins.

Q. And Exhibits No. 1 and 2 represent the complete opinions you're prepared to give in this case; is that fair?

A. That's correct.

Q. I show you now what's been marked as deposition Exhibit No. 3. That's a Notice of Deposition in this case.

A. Yes, I do see it.

Q. Have you seen that before today?

A. Yes, I did.

Q. As a part of Exhibit 3, there's a request attached to it that you produce documents in response to that.

A. There are 27 requests. Yes, I've seen that.

Q. Did you review those requests?

A. Yes, I did.

Q. Did you attempt to collect the

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information contained in those requests and produce it to me today?

A. Yes, I gathered all what I could on the thumb drive.

Q. And counsel has given me today what I've marked as Exhibit No. 4, which is a thumb drive. Is this the thumb drive that you just described where you attempted to load all of the documents responsive to the Notice of Deposition that you could find to put on the thumb drive?

A. That is correct.

MR. ORENT: At this point I want to place an objection and notification. We did file a written objection so subject to those written objections that material has been produced.

BY MR. THOMAS:

Q. To save the time of going through the notice or the thumb drive for right now, can you recall any documents responsive to the Notice of Deposition that you did not include on the thumb drive?

A. Well, the communication with lawyers I didn't put.

Q. Okay.

A. The rest, I think I included

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everything I had pertinent to this case.

MR. ORENT: Just to clarify though again, the communication, I believe, was outside of the three areas specified on Number 27.

MR. THOMAS: I'm sorry, I did not hear you.

MR. ORENT: Under the federal rules your request Number 27, to make the federal rule recognizing the privilege existing between expert and attorneys.

With the exception of the three areas that you requested, I believe there were no responsive communications specifically to those three areas.

I believe other communications exist that are not discoverable, and that's what the doctor is referring to.

MR. THOMAS: Okay.

MR. ORENT: I don't believe he withheld anything responsive to the request as written.

BY MR. THOMAS:

Q. Doctor, you've given depositions before in the Ethicon MDL, correct?

A. That is correct.

Q. You've testified in connection

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with the Bellew case?

A. Yes, I did.

Q. And you've testified in connection with the Huskey and Edwards cases, correct?

A. That is correct.

Q. And in those depositions you testified to a methodology that you used to collect specimens, create histopathological slides where appropriate and review those slides.

Did you follow the same process in the Mullins case that you followed in the Bellew and Huskey Edwards cases?

A. The process is standard. It's not specifically for medical-legal cases or mesh cases. It's a standard histology protocols in a diagnostic pathology lab, so I don't change it. I follow them for each specimen regardless if it's medical-legal or a regular hospital patient.

Q. Doctor, my question really meant to eliminate re asking all those questions that were asked in Huskey, Edwards and Bellew.

And if we can confirm that you followed the same procedures in the Mullins case that you followed in the prior depositions where you were asked about your procedures then I'm not going to

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go over that again. Can we confirm that you followed the same steps?

A. Yes, I can confirm that.

Q. Doctor, what is a neuropathologist?

A. Neuropathologist?

Q. Yes.

A. Neuropathologist is a surgical pathologist who is specializing in examining brain tissue or spinal cord. Sometimes it's the subspecialty people do just neuropathology; sometimes there is cross-coverage.

In our institution we have a neuropathologist but it's only one. Sometimes he goes away on meetings, so we cover neuropathology.

Q. Are you a neuropathologist?

A. I'm cross-covering neuropathology when he is away but I have not specialized in neuropathology.

Q. Are you board certified in neuropathology?

A. No, and you don't have to be board certified in neuropathology because surgical pathology includes neuropathology.

I mean, you can sub specialize further down, but it depends on specific institution.

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Because some institutions have a large number of specialized cases and some institutions they cover broad range.

Q. You said you had a neuropathologist at St. Michael's?

A. Yes, we do.

Q. What is the person's name?

A. Dr. David Munoz.

Q. Is that the only neuropathologist at St. Michael's?

A. Right now, yes.

Q. Did you consult with Doctor -- what's his last name?

A. Munoz.

Q. M-U-N-O-Z?

A. Yes.

Q. Did you consult with Dr. Munoz in connection with any of the opinions that you've given in this case?

A. No.

Q. Did you consult with any neuropathologist in connection with the opinions you've given in this case?

A. We're not talking about brain tumors; we're talking about sub tissue transvaginal. I mean, why would I consult a neuropathologist?

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Q. Just a simple yes or no question?

A. No, I didn't. There was no purpose.

Q. Did you consult any neuropathology textbooks in connection with your opinions in this case?

A. Specifically just recently?

Q. Any time during your work in this case?

A. Not in this case. I opened and read several neuropathology books when I was doing research in meshes. It's not just neuropathology books, I mean, neuropathology is described in general surgical pathology books. Because I've been in this field for three years.

Q. I understand. Just specific questions, we'll get done quicker if you answer "yes" or "no", if you can, and I'm not trying to pin you down.

Is it your belief that neuropathology has no role in understanding the presence of nerves in the pelvic floor?

MR. ORENT: Objection to form.

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THE WITNESS: Yeah, actually the form of the question is quite bizarre.

Because neuropathology is part of surgical pathology. So I'm a surgical pathologist I'm examining -- yes, there is a field of neuropathology when you specialize in that.

If you take a combination of peripheral nerves as part of neuropathology, then I can say yes, there is a part of neuropathology. But as I said, it's still within surgical pathology.

This separation is somewhat artificial. You probably don't understand exactly how such specialization works. Probably that's where it's coming from.

BY MR. THOMAS:

Q. Perhaps. Do you know a Kenneth Aldape, A-L-D-A-P-E?

A. No.

Q. Lorraine Kalia, K-A-L-I-A?

A. No.

Q. Julia Keith?

A. No.

Q. Tim Rasmus Kiehl, K-I-E-H-L?

A. The names might be similar. I mean, a couple of those names are the same as a

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couple of neuropathologists in Toronto, I believe, but I don't know their first names.

Q. My information is these neuropathologists are affiliated with the University of Toronto.

A. Yes, so Dr. Kiehl is practicing at UHN and I think there was another name that also practices at UHN. It's a different institution. The U of T affiliated hospital is called UHN.

Q. There's special neuropathology journals, aren't there?

A. Yes, there are.

Q. Do you subscribe to any?

A. No.

Q. So fair to say you don't serve on the editorial board of any neuropathology journals, true?

A. No, that's true.

Q. Is there any reason for you to consult with a neuropathologist to understand how nerves function in the pelvic floor?

A. Not really. The only reason I would go to a neuropathologist when there is something I don't know and I cannot find answers in regular books, something which comes from

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experience. We are talking about basic function.

Q. In Canada, is there a board certification for your position as anatomical pathologist?

A. Yes, there is.

Q. Is there a board certification for neuropathologists?

A. I'm not sure, but we are practicing neuropathology with this anatomical pathology certification.

Q. As far as you recall, you haven't consulted with any neuropathologists in connection with your work in this mesh litigation; fair?

MR. ORENT: Objection.

THE WITNESS: Not for this specific case. Earlier, when I started research, I ask a few questions which stain sometimes it was better to use when there is pathology of nerves.

BY MR. THOMAS:

Q. Who did you ask?

A. Dr. Munoz, but I think it was even before the litigation started.

Q. And what did you ask Dr. Munoz?

A. Which stains he was using, if he was using something different that I was using.

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Q. And what question did you ask him? What stain do you use for what?

A. When we started our research in meshes, the question was, if the nerve's ingrown. So this is kind of basic question.

Q. Sorry, if the nerves what?

A. Grow into the mesh. So this was a basic question. But then I was thinking, okay, so I need to make sure that I'm not missing anything and I started thinking of possible scenarios, how nerves can be affected by the mesh.

Are they going atrophic, can they disappear completely? And if they go atrophic, you can see atrophy in the nerve with any stain, because the area becomes empty, sort of ooze, the Schwann cells disappear, their axons, this is a basic knowledge.

And I ask him if he's using something else, and he was using exactly what I was using.

Q. So is it fair to understand that you confirmed with Dr. Munoz your choice of the S100 stain for nerves?

A. No, that was not about the S100.

Q. What stain specifically was it about?

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A. If anything else he's using to examine nerve atrophy or degeneration.

Q. And what were you using to analyze that question?

A. Just locating H&E.

Q. And Dr. Munoz said that was what he was using to analyze the same question?

A. He said that you can see it on H&E, but there are a number of other stains to examine for nerve atrophy.

Q. And what stains did he tell you that you could use, other than H&E?

A. Well, you can see some of the atrophy on S100 -- I don't remember exactly what he said because it was three years ago, because now what I remember it might be coming from different sources, so from my own experience.

Q. Do you have a specific recollection of talking to any neuropathologist who gave you any information about how to conduct your investigation into these meshes?

A. I don't understand your question.

Q. You've told me about conversation you had with Dr. Munoz. Do you have a specific recollection, you remember having any conversations

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with any neuropathologists about how to conduct your work in these cases?

A. Why would I?

Q. I'm just asking you if you did or not?

A. No, I didn't.

Q. Thank you. Now, Exhibit No. 1 and Exhibit No. 2 are your reports in this case; we talked about that already. They contain a number of images?

A. That's correct.

Q. Have you supplied copies of all those images on this thumb drive?

A. No, because they're already included in the report. I can produce them for you separately.

Q. Do you have digital images of the slides in this report?

A. Of course.

Q. But they're not on the thumb drive?

A. No, because they're already in the report.

Q. Do you have images of the tissue samples that are contained in the report that are

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not in the report?

A. But we took those images together with your expert.

Q. I'm just asking you if you have them?

A. I should have them, yeah.

Q. Okay?

A. Because we were taking them -- he would take picture. I would take picture of the same field.

Q. But there are images that you have of the tissue samples that are contained in your report that are not produced on this thumb drive, correct?

MR. ORENT: Objection.

THE WITNESS: There should be. I was not using them. I was just recording together with your expert when I received the specimens.

BY MR. THOMAS:

Q. Okay. And if you go to -- let me just ask this question.

What is the source of the images that are contained in your report? Where did you get them?

A. I took them.

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Q. Okay. And from what tissue samples did you take them?

A. From explanted TVT and TVT-O meshes.

Q. How many TVT?

A. Oh, that I would have to check with my records now. I don't remember now.

Q. And TVT-O?

A. It's there, but I don't remember now.

Q. And the TVT and the TVT-O specimens that are contained in your report are that, are those specimens from the set of specimens that you obtained from Dr. Klinge?

A. No. It's a combination of earlier medical-legal cases, patients of St. Michael's Hospital, and samples which came within this consolidated trial.

The earlier cases came from different law firms.

Q. Do you know what I'm referring to? You talked about the Bellew case, the set of slides that you received from Dr. Klinge, and Dr. Kreutzer, 22 TVT and TVT-O samples?

A. My recollection is I was contacted

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by Anderson Law and I'm not sure when -- I don't remember exactly where the package came from, but all my communication was with the Anderson Law.

Q. I understand that, Doctor, but in the Bellew case you testified at length about a set of 22 TVT and TVT-O samples that you had received from Mr. Anderson that had previously been reviewed by Dr. Kreutzer and by Doctor Klinge?

A. Kreutzer for sure; I'm not sure about Doctor Klinge. There were no records, or maybe there was records but I just don't remember them.

I didn't contact specifically Doctor Klinge, or he didn't contact me specifically about these samples.

Q. Are the images of the TVT and the TVT-O slides that are in your report in this case from the same set of slides that Dr. Kreutzer reviewed?

A. Some of them could be. Again, I don't remember now. It would be difficult to trace them back.

Q. Do you have somewhere a key that shows whose tissue this is in the report?

A. In the report, the way the images

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were saved during my work, they would be usually saved in folders for specific expert report.

Q. Let's go to page 19 of your report, please, Exhibit No. 1?

A. So if we open these images, I specify if the image is coming from consolidated trial cases, which I received just recently, or if the images are of additional cases, and additional I meant previous TVT and TVT-O cases which I received during the course of my work on expert of possible Bellew case and others.

Q. How many consolidated cases do you have images for, individual plaintiffs?

A. Like four, three. Three, four. Some specimens came as bare mesh, had difficulty embedding -- well, we embedded them but there was not much in there.

Q. I understand. I'm just trying to understand what you're working from.

So you have three or four tissue samples from plaintiffs in the consolidated cases, correct?

A. That is correct.

Q. What kind of mesh is that?

A. TVT or TVT-O.

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Q. Okay. And so in your report, where you refer to images of consolidated cases, is it fair to say that those images come from the three to four tissue samples that you got from the consolidated cases?

A. That's correct.

Q. If you go to page 21?

A. Yes.

Q. Page 21 identifies in Figure Set 1c, images of additional TVT cases; what does that mean?

A. That means this image comes from previous TVT and TVT-O cases, or cases I received previously.

Q. Can you tell by looking at this whether it's a medical-legal or whether it's something that came through St. Michael's?

A. It would have to be sort of picture matching. I would have to open the folders which contain previous reports.

It all depends how the figure was taken. If it was taken by older camera, it didn't record the case number.

Now, for some newer cases the images were scanned and when the scanner works, there is

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embedded surgical number.

Because they're all spread within almost three years, some of them can be traced; some of them would be difficult to trace.

Q. Is it fair to understand that looking at the report, where you identify images from additional TVT cases, you're unable to tell me from what case that image comes from?

MR. ORENT: Objection.

THE WITNESS: In some cases I can, and some cases I cannot. I can tell that you all of them came from TVT and TVT-O because I kept strict records for that.

But I didn't keep strict records for specific cases, at least at the beginning.

BY MR. THOMAS:

Q. Okay. In those places where you can identify the patient, did you do so in your report?

A. No.

Q. Why not?

A. But they are not in this trial -- and they may be confidential. And why would I?

Q. But there are images in this report that don't have identifying information --

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none of them have identifying information?

A. They have one single identifying information which is important: TVT or TVT-O. Everything else doesn't matter.

Q. But I can't take this, go into your file and figure out where this slide is, can I?

A. I'm telling you it's all TVT and TVT-O. What else do you need to know?

Q. Am I able to take this thumb drive and figure out which slide is which patient on page 21?

MR. ORENT: Objection. I think what the doctor is explaining is that these are all from prior reports served on you.

THE WITNESS: Most of them are. You can go to older reports and find them.

BY MR. THOMAS:

Q. Why didn't you say "from the Edwards case" to tell us where it came from?

A. Why would I? I don't understand the question. I mean, this is an opinion about TVT and TVT-O.

I am not making an opinion about Edwards or any other specific patient. I am giving

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you opinion about TVT-O as a product.

Q. Do you maintain your sets of these slides by individual plaintiff?

A. In some cases, yes. If there is a generated report because that is a specific plaintiff, I save them as separate folder.

But remember those 23 or 22 cases when they came as a bulk and I did not produce any specific reports for specific patients, individual patients. They were all saved in one folder.

Q. Okay?

A. Which was just additional -- didn't keep record for that.

Q. Are the files on this thumb drive, Exhibit 4, marked by individual plaintiff?

A. No. As I said, I didn't include figures because they were included in the report already.

If you want me to include these specific figures, I can do that. But it will not be possible to trace specific picture, specific patient.

And that was not the purpose because the purpose was to give an opinion about TVT-O or TVT as a product, not to give opinion for specific

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plaintiffs.

Q. Exhibit No. 2 is a supplemental -- micro photographs. You identify those as from the specimen of Ms. Elizabeth Mullins?

A. That is correct.

Q. Is Elizabeth Mullins -- strike that. Did you share this tissue with Ethicon?

A. Yes, I mailed it a week ago.

Q. Why did you identify this by patient name and not identify the others in your report by patient name?

A. Because it was a single case specifically supplemented for one specific patient.

Q. So this is one of the three or four TVT, TVT-O cases that you reviewed for consolidated plaintiffs?

A. Might be an additional to the three or four.

Q. Okay?

A. So it could be fifth, or fourth.

Q. Okay. Do you expect to receive any more tissue samples from the consolidated plaintiffs?

A. No. As far as I would understand this is all what we have at this point.

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Q. For the original tissue samples that you received from Dr. Kreutzer, the 22 or 23 TVT or TVT-O, did you know that those samples, tissue samples, were also analyzed by Dr. Jordi, using analytical chemistry?

A. The name sounds familiar but I don't know details. I don't remember, sorry. I don't remember specific details, what was done in that time.

Q. Have you ever seen any analytical chemistry testing on the 22 or 23 TVT samples that you received from Dr. Kreutzer?

A. I don't recall specific details. I could have seen something, I could have not, it's been quite a long time ago.

Q. Did you ever request that analytical chemistry testing be conducted on any of the mesh samples that you've analyzed?

A. No. I have my own methodology in this; I describe what I see. Why would I ask somebody else to do something else?

Q. So is it fair to understand that for Exhibits Number 1 and 2, which is your report and supplemental report, that all of the images in here are TVT or TVT-O manufactured by Ethicon?

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A. Yes. Some images were taken from publications, so there was one or two panels from different mesh manufacturer.

But the rest, when the pictures were individual, they were all of TVT or TVT-O explanted specimens.

Q. Are you able to tell me sitting here today -- strike that.

Let's go to Exhibit 3, please. Number 15?

A. Yes.

Q. Number 15 asks for all materials including but not limited to any protocol specimens, slide raw data interim and final test results, log laboratory books, notes, photographs, photo micrographs and any other documents relating to the pristine polypropylene control you tested by exposure to formalin for up to four months referenced on page 17 of your report in this case.

Is there any information on the thumb drive from Exhibit 4 for that?

A. The entire protocol is really simple. It was included in the paper, so it is on the thumb drive; the paper is on the thumb drive. I didn't have anything in addition to that.

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Q. Is there any lab notebook?
A. No, I mean --
Q. Are there any photographs?
A. All photographs I had, I included there.
Q. So whatever you have related to the formalin exposed polypropylene control is on the thumb drive?
A. In the report. The pictures are on the report. The paper with description of the experiment is on the thumb drive.
Q. What kind of polypropylene was tested with formalin?
A. What do you mean, what kind? I tested meshes of different manufacturers including Ethicon TVT.
Q. So you did use an Ethicon Prolene mesh in the formalin control test?
A. It was TVT.
Q. Okay.
A. It was a piece of TVT, a few pieces of TVT put in formalin.
Q. When you say you put it in formalin, did you do anything other than just put it in a jar?

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A. They were kept in formalin, in a jar, and then they were put in the cassette for tissue processing and then they went through the whole process of xylene alcohol and everything else and then I had slides made.
Q. And no analytical chemistry done of that control, correct?
A. Why would I? I'm doing histology.
Q. I understand. No analytical chemistry; is that correct?
A. That is correct.
Q. Thank you. Number 19.
A. Yes.
Q. "Request all materials related to testing of intentionally oxidized polypropylene that had not been implanted or exposed to formalin." Do you see that?
A. Yes, I do.
Q. Is there any information on Exhibit No. 4 related to that kind of testing?
A. No, because the test is still in progress. I mean, I kept part of mesh in different solutions and I haven't taken them out yet. I haven't examined them yet.

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Q. Okay. Tell me what that experiment does?
A. I did the same thing as I did for formalin exposure. I took pieces of mesh and put them in solutions of hydrogen peroxide, hydrogen peroxide with catalysts, few strong acids, solvents, and just they are stored in these solutions.
Q. How many pieces of mesh are you testing?
A. It's hard to say now. It might be over 20 small pieces.
Q. And how are they stored right now?
A. In a dark room in a cabinet.
Q. In a vial?
A. What do you mean, vial?
Q. Are they in a container with a cover on them?
A. Yes, of course. Some of them are acids and they're in glass containers.
Q. What temperature are they being stored?
A. Just room temperature.
Q. Do you have a protocol that you wrote up for this test?

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A. No. The only protocol I used was there was a published paper, they introduced this stimulated body environment -- simulated, not stimulated. Simulated body environment. Hydrogen peroxide was the catalyst. Catalyst is a chromium salt.
Q. Cobalt chloride?
A. Probably.
Q. That's Dr. Guelcher's paper?
A. I'm not sure if it's his paper, it's another paper. But anyway, I'm testing his protocol. I followed exactly the description in the paper and kept it in the solution for almost a year by now, but it's still too early to take it out.
Q. Why is it still too early to take it out?
A. Because based on my analysis of the specimens explanted from the body I can barely see the degradation bark after a year in the body. So if I take them now it would be too early.
I may just waste samples, so I have to wait for probably a few extra months or maybe another year. Because by year two or 1 1/2 years in the body, the bark becomes visible in

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100 percent of the cases.
If I take them out by 12 months, I may or may not see something and then it would -- I'll just waste samples.
Q. Did you prepare the solution in which these samples are stored?
A. Yes, I did.
Q. And what is the recipe for the solution that you used?
A. It's written in the original paper I used for the --
Q. Can you tell me what the original paper is?
A. I'd have to check now.
Q. And how many samples are stored?
A. As I said, probably over 20.
Q. And how many different kinds of mesh are being tested?
A. There is one from one manufacturer, and then -- four types of mesh.
Q. How many Ethicon meshes are being tested?
A. At least one.
Q. What kind?
A. It's written on the jars. I may

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have to check later.
Q. Doctor, do you have an inventory of what's in each vial written down?
A. It's written on the jar.
Q. Is it written down on a piece of paper anywhere?
A. No.
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Is it written in a computer somewhere?
A. No, just on jars. Jars label when the case was put and what type of mesh was put in.
Q. When did you start this experiment?
A. Last September.
Q. So it's been a full year?
A. Yes.
Q. And did you put the mesh in this solution in these 20 or so samples all at the same time?
A. Within two weeks.
Q. All right. As I understand it, there are at least four different mesh manufacturers that are a part of this experiment?

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A. At least four different type of mesh. I would have to check with the labels what is written there, what manufacturers, what mesh was put in there. I don't remember. It's been a year.
Q. Are you working with anybody else on that experiment?
A. No.
Q. This is solely your work?
A. Yes.
Q. Did you consult with anybody about the kind of solution that you would use for your experiment?
A. No. Whom I would consult? Nobody did it before. The only information I extracted was from that specific simulation body environment simulation from the paper.
Q. You know Dr. Guelcher has tried to insulate oxidized polypropylene, don't you?
MR. ORENT: Objection.
THE WITNESS: I know that he did an experiment, and he asked me what I see. I said it's too early, I'm not going to take them out yet. I will keep them a little longer.
BY MR. THOMAS:
Q. Did Dr. Guelcher tell you he had

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intentionally oxidized polypropylene by exposing it to some chemical solution?
MR. ORENT: Objection.
THE WITNESS: Yes, he did.
BY MR. THOMAS:
Q. Did you ask him to have that mesh so that you could determine whether this intentionally oxidized polypropylene absorbed stain?
MR. ORENT: Objection.
THE WITNESS: No.
BY MR. THOMAS:
Q. Why not?
MR. ORENT: Objection.
THE WITNESS: Because I'm doing my own experiment and I believe I need to keep it for at least a year and a half.
BY MR. THOMAS:
Q. Did you discuss with Dr. Guelcher the scope of his experiment?
MR. ORENT: Objection. At this point, Counsel, I think you're getting into -- I think you need to clarify whether your questions are in the context of litigation or research.
To the extent it's in litigation it's

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covered by privilege and I would instruct the witness not to answer under the rules. But to the extent that you're discussing research, I think that's fair game to discuss.

BY MR. THOMAS:

Q. Okay. From a research perspective, did you have any discussions with Dr. Guelcher about his experiment?

A. It's work in progress so it's privileged to researchers, I guess, at this point.

Q. Are you going to assert a privilege for your research?

A. For research information, yes.

Q. Okay. And you asserted a litigation privilege, which I don't think is appropriate -- I'm not arguing with you. You said there's no research privilege. Now he's trying to assert a research privilege?

MR. ORENT: No, what I said was in terms of legal -- in terms of legal privileges that I can, that I have, that I have an attorney-client -- excuse me, a attorney work product under the Rule 26.

Rule 26 specifically allows for expert witnesses to consult with one another under the

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2010 amendments to the federal rules.

So, what I was clarifying is that it is my privilege to seek and to utilize for my client, and that's what I was exercising with regard to non-research thought processes for litigation.

To the extent Dr. Iakovlev has proprietary interests in research that is ongoing or may be ongoing, that's up to him as to whether or not -- and I know that on both sides in this mesh litigation have previously taken a position that those sort of things are not discoverable.

To the extent the doctor is comfortable, I'd be happy to designate this portion of the transcript highly confidential and allow the witness to answer.

THE WITNESS: I also need to add that that experiment is not in my opinions. I was not base my opinions on any part of that experiment. And I'm not really sure why you asking me these questions.

BY MR. THOMAS:

Q. Because I get to ask them.

MR. ORENT: If I can just have a minute with the witness and explain what the highly confidential designation means, that may clarify

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this.

MR. THOMAS: Thank you.

-- RECESS AT 9:42 --

-- UPON RESUMING AT 9:43 --

MR. ORENT: We can go back on the record.

I'll just say for the record over the break I just explained to Dr. Iakovlev what the highly confidential designation is and that all the lawyers in this litigation have all signed on to it.

Confidentiality agreement whereby there are limited distribution on each side as to who can receive highly confidential information and that after discussing it I believe the witness is comfortable with the designation and will proceed to answer.

BY MR. THOMAS:

Q. Thank you. Have you have discussed with Dr. Guelcher the results of his test?

A. Yes, I asked him what he saw.

Q. And what did he tell you?

A. He said that there is flaking on the surface early, it's not confluent but there are

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some flakes forming.

I said it might be too early, because he did it I think on six weeks or so, maybe more, maybe up to three months.

I said, well, I keep my specimens for at least a year and a half because I believe that that's much time you need to make it visible by my techniques. Maybe by SCM we can see a little bit earlier, and we stopped at that.

Q. Do you know whether he conducted any analytical chemistry testing on any of the mesh he analyzed?

A. I think he did.

MR. ORENT: Objection.

THE WITNESS: I don't remember at this point. It's not my specifically methodology, so I didn't do these things.

BY MR. THOMAS:

Q. Did you have discussions with Dr. Guelcher about trying to stain the polypropylene that he had intentionally oxidized?

A. He asked me. I said it's too early.

Q. Okay?

A. So I said maybe by your methods

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you can detect it. By my methods, probably I cannot. And I said I will keep my pieces for longer and then we'll see what happens.

Q. And how did you decide -- strike that. Did I understand you to say that you have chosen 18 months as the time when you think it will be appropriate to test for oxidation?

MR. ORENT: Objection to form.

THE WITNESS: Yes.

BY MR. THOMAS:

Q. And at 18 months is it your intention to remove all of those meshes from the chemical solution and determine whether it's intentionally oxidized?

A. Part of it. Probably not all of them in one shot. I will start taking some pieces and examining them see what happens and if I -- depends on what I see, I may keep them longer.

Q. And what kind of tests do you propose to run on them after 18 months?

A. Histology, what I've done -- what I showed in the paper.

Q. The same kind of tests that you've run on the meshes that are contained in your reports?

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A. Similar.

Q. Any differences?

A. Don't plan on anything different at this point. I may, I mean, it's work in progress research. Maybe I'll find something else, I don't know.

Q. Are you consulting with anybody else on this particular experiment?

A. We discussed it only with Scott Guelcher.

Q. And is the mesh that's being tested pristine new mesh?

A. Yes.

Q. Never been exposed to tissue?

A. That is correct.

Q. Never been exposed to formalin?

A. That is correct.

Q. Who is paying for this testing?

A. Nobody. I just took chemicals from our histo lab.

Q. Did counsel fund this experiment?

A. No, there is no additional funding. What funding would I need for it? Chemicals are in the lab.

Q. Where did you get the mesh?

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A. They came from some law firms during earlier cases.

Q. Okay. And where did you get the chemicals?

A. I said, they are in the lab.

Q. Okay. So you used materials from the St. Michael's histo lab to put them, and you combined those chemicals in a recipe that you're now exposing this polypropylene to?

A. That is correct. These are regular chemicals that are used in histo lab.

Q. And the reason why you're doing this test is to determine whether, first, after 18 months this polypropylene will oxidize due to exposure to this chemical mixture, correct?

A. Could you repeat the question?

MR. THOMAS: Can you read it back?

-- REPORTER'S NOTE: Question read back as recorded above.

THE WITNESS: That's correct.

BY MR. THOMAS:

Q. And how will you determine whether it's oxidized?

A. I would see degradation layer on the surface.

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Q. And that would be by light microscopy?

A. Yes.

MR. ORENT: Objection.

BY MR. THOMAS:

Q. Any other analytical technique that you propose to use?

A. As I said, none at this point.

Q. And as a part of your experiment do you then intend to see whether -- if you are able to oxidize polypropylene, according to your visual observation by light microscopy, will you then see whether the oxidized polypropylene holds stain?

A. Yes, that's the way to see it. This just becomes porous and after absorbs stain.

Q. And the way you will test that is the same way you've processed the slides in Exhibit No. 1 and 2 -- you'll put them through the sample preparation histology analysis that you've done in all your other cases?

A. Can be tried without putting them through histology; you can immerse exposed mesh into the dye solution.

Q. Just drop it in the jar?

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A. Pretty much. If it stains, then you can see staining on the surface. That means there is a layer of porous polypropylene on the surface.

It's like, this is not stain, this is anodized aluminum. So there's porous layer on aluminum. If you drop unprepared aluminum in the jar with black ink it will not absorb anything because it's sealed.

If you drop it with anodized layer it will become black because it will absorb it. It's the same technique; it's pretty basic.

Q. I understand. Thank you.

Are you aware of a method where you can take a piece of pristine mesh that's been exposed as you've described, and prepare a histological slide of that exposed material without embedding it in some other medium?

A. Let me ask you if I got your question right.

Am I aware of a histological technique which will allow me to cut through the mesh without embedding it into anything?

Q. Correct.

A. No. It has to be embedded into

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some form of medium to hold it for the knife to cut through.

Q. Have you devised or thought of a method to do that?

A. No. Why would I?

Q. If you're going to do a histology slide of this mesh that's been exposed to chemicals after a year and a half, you're going to have to put it in some medium before the microtome can cut it, correct?

A. Paraffin.

Q. So you're going to put the mesh by itself in paraffin and cut it from there?

A. Yes.

Q. Okay.

A. That's how it's done.

Q. That's fine. Doctor, on page 82 of your report?

A. Yes.

Q. Are you on page 82? That's where I want you to be.

A. Oh, yes, okay.

Q. I'm sorry, 83. I apologize, I was wrong.

Page 83 of your report has two images,

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A and B, identified as Figure Set 16 A, is identified as "cracking on the surface of TVT mesh fibers immediately after removal from the body".

Where did you get this?

A. This was a St. Michael's patient. So when it was excised I immediately placed it under the microscope.

Q. How did you know it was being excised?

A. What do you mean how do I know? We receive specimens.

Q. Just so I understand -- strike that.

Typically after a surgical procedure when mesh is excised the surgeon immediately places it in formalin, correct?

A. Not always.

Q. Okay.

A. We receive it fresh, so in this case it was fresh.

Q. And did you discuss with the surgeon any of the circumstances of removal?

A. This was a St. Michael's specimen, so I did ask, but I'm not sure if I can go there because of the confidentiality issues. It was not

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a medical-legal case.

Q. Who was the doctor that you discussed it with?

A. I don't know if I can disclose it.

Q. I'm going to ask you to and if you tell me no, you tell me no?

A. Again, I'm not sure if I can disclose that because it is confidential information.

Q. Are you telling me you're not going to? That's fine. Tell me you're not going to and I'll move on.

A. No, I will not. I will not because I don't want to compromise confidentiality.

Q. Okay. Can you tell me the nature of the conversation you had with this doctor?

A. Oh, I asked her later on what was -- because then I would ask how long it's been in the body, some information was on the records and just basic information.

Q. Did you get medical records for this mesh?

A. It was in medical -- in the medical records of St. Michael's Hospital.

Q. Did you produce on the thumb

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drive, Exhibit No. 4, the medical records for the patient that's on page 83?

MR. ORENT: Objection.

THE WITNESS: No, it's confidential information, St. Michael's Hospital information. And the picture is not coming from a case itself; picture is coming from a publication.

BY MR. THOMAS:

Q. Well, it's your publication; is that fair?

A. Yes.

MR. ORENT: Objection.

BY MR. THOMAS:

Q. Okay?

A. But it's not coming from a set of TVT or TVT-O cases which are received within the litigation process. It's coming from a publication and for that publication I had REB approval and there are strict rules what can be disclosed, what cannot be disclosed.

Q. How long from the removal of this mesh until the time you looked under the microscope?

A. I would say an hour, maybe 40 minutes, maybe less.

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Q. How did you manage to get it so quickly?

A. We have a lab in the OR. OR is practically -- I mean, our receiving area for specimens is in OR, it's like there.

Q. Did you tell the doctor if she ever got a TVT specimen that you'd like to have it before it was put in formalin?

A. No, but I told, I told several physicians and several -- everybody knows that I'm working on meshes, so people know that I'm interested in meshes.

Q. My question was, did you tell a doctor to give one to you before it was exposed to formalin?

MR. ORENT: Objection. Can I just ask for clarification. Your prior question was -- included the word TVT. Prior testimony on this was that this was not a TVT, I believe. Oh, this is a TVT, I apologize.

THE WITNESS: In the earlier, very early when we started working on these meshes, the question was how do I process them for scanning of -- transmission of electron microscopy, and I needed fresh samples.

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Not only specifically for this case, I asked if you can sometimes help me with what you're excising, or submit it in saline, so it's not exposed to formalin because I needed samples to be put in a glutaraldehyde. This came in saline.

BY MR. THOMAS:

Q. Was this put in glutaraldehyde before you made this image?

A. No, it was put in saline. I received it in saline, I examined it, took pictures and put it in formalin.

Q. Other than putting it in saline, was any effort made to clean the mesh prior to the time that you took these images?

A. No, just washed them in saline, that's it.

Q. Was it washed in saline or just soaked in saline?

A. What's the difference?

Q. Well, there was no effort to wash it, it was merely stored in saline before you took your images; is that fair?

A. You immerse something in fluid; it's being washed.

Q. Okay. Go to page 5 of your

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report, please.

A. Yes.

Q. Down at the bottom of the page, the sentence, it reads:

"Immediately after placement in the body, foreign objects become coated with human proteins before appearance of the inflammatory cells."

Do you see that?

A. Yes.

Q. What does that mean?

A. It means that anything you put in the body will get coated by serum proteins.

Q. How many different kinds of proteins are there in the body?

A. Very large number, thousands, maybe millions.

Q. Is there a special kind of protein that surrounds the foreign body?

A. It's non-specific. The area will be filled with blood immediately, so main proteins are in the serum, so it will be albumin, some immuglobins, then the blood clotting cascade sets in.

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So there will be more of a fibrinogen and fibrin, all of those proteins which are involved in blood clotting. It depends what timeframe we're talking about, immediate coating, or minutes or hours or days after.

Q. Do you know what protein adsorption is, A-D-S-O-R-P-T-I-O-N?

A. You mean adherence of the protein to the surface?

Q. Are you familiar with that?

A. I mean, that's the term as I understand it.

Q. Do you know chemically how that works?

A. For all proteins?

Q. For protein adsorption to foreign bodies; do you know how it works?

A. Not the specific chemical details.

Q. Do you know the extent to which the proteins form a bond with the foreign body?

A. Not the specific details.

Q. Do you specifically with polypropylene -- or strike that. Specifically with Prolene, do you have any information about the extent to which human proteins form a bond with the

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Prolene polypropylene?

MR. ORENT: Objection.

THE WITNESS: No.

BY MR. THOMAS:

Q. Do you have any information about the extent to which saline is adequate to remove any proteins that are adsorbed on to the Prolene mesh?

A. No, I think it's irrelevant because that mesh which was examined didn't have time to dry and couldn't dry because it was in saline.

So if it cracks it means that it had time to crack. In this case it couldn't dry.

Q. There's no analytical chemistry done on this, correct?

A. No.

Q. There are none; am I correct?

A. You are correct.

Q. Thank you. So, you're basing your opinion on the cracking, which you claim to be the Prolene, based on your visual observation?

A. That is correct.

Q. Let's go back to page 82, please which is your statistical analysis of TVT meshes

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analyzed as groups?

A. Which page number?

Q. I'm on 82.

A. Okay.

Q. 82 is called, "Figure Set 15, TVT Meshes Analyzed as a Group".

And you're doing a statistical analysis here of the TVT meshes; is that correct?

A. That's correct.

Q. Are the TVT meshes described on page 82 the meshes that you got from Dr. Kreutzer?

A. Some of them.

Q. How many of them?

A. I don't remember now. Probably about 20 or 19.

Q. And how many are in this group?

A. 23.

Q. So probably 19 or 20 out of 23 were meshes you got from Dr. Kreutzer?

A. Probably, but I'm not sure. I don't remember now.

Q. Are you a trained statistician?

A. No, but I had my statistics when I did my research training.

Q. Okay. Who chose the statistical

Page 57

method that's employed here?

A. I did.

Q. And why?

A. What do you mean why?

Q. Why was this method the method you chose?

A. Because it's the method to check what I was intending to check.

Q. And tell me why that is an appropriate method for what you have done?

A. What do you mean?

Q. Why is this Pearson coefficient?

A. Pearson coefficient? It's a standard correlation coefficient method.

Q. Are you aware of other statistical methods to test your results?

A. What do you mean? For correlation?

Q. Yes.

A. Could be Spearman.

Q. Spearman?

A. Yes.

Q. Any others, R-squared?

A. For correlation?

Q. Yes.

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A. There might be others, but the main are Pearson and Spearman; there is not much difference between them.

Q. Is the raw data you used to do your statistical correlation on Exhibit 4?

A. Yes, it is.

Q. And how is it marked, so if I wanted to find it, I could see it?

A. It's in a separate file it's called 23 TVT-O and something else for the chart.

Q. So if I wanted to have a statistician run a different model, all of the data he would need to do it is on Exhibit 4?

A. Yes. It's there.

Q. Okay. Doctor, since you were last deposed, you've had a couple of studies published in journals?

A. Probably more than a couple, yes, I did.

Q. And your deposition notice requested communications with the journals about publications that you produced. Are those on Exhibit 4?

MR. ORENT: Objection.

THE WITNESS: I believe it's

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confidential to me as a researcher, privileged. They've been published, they've been accepted, they are publicly available.

BY MR. THOMAS:

Q. Is the answer to my question no, you didn't produce any of those communications?

A. No, I didn't.

Q. Do you have such communications?

A. Acceptance letters, that's about it.

Q. Do you have any comments or criticisms from any peer reviewers?

MR. ORENT: Objection.

THE WITNESS: There were some.

BY MR. THOMAS:

Q. Do you still have those?

A. Yes, I do.

Q. Were any of these articles rejected by any journals?

A. Sometimes I submit to one journal they say it's out of scope it's probably best suited for another journal so it bounces back.

I don't remember specific rejection, saying that the data isn't reliable. The only way -- the only time when the paper was not accepted it

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was quick answer, right away, that's not in our scope.

Q. So how many journals did not accept your publication?

MR. ORENT: Objection.

THE WITNESS: I don't remember now.

BY MR. THOMAS:

Q. Okay. Do you have that information?

A. Probably somewhere in the replies I can find it.

Q. Okay. Did you ever disclose to the journals to which you submitted these publications that some of the work contained in the journal publication had been funded by plaintiff's counsel?

MR. ORENT: Objection.

THE WITNESS: Nothing was funded by plaintiff's counsel. They were litigation cases but I didn't get any additional funding to conduct the study.

BY MR. THOMAS:

Q. Certainly the slides from Dr. Kreutzer were provided to you by plaintiff's counsel?

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MR. ORENT: Objection, argumentative.

THE WITNESS: I didn't use them.

BY MR. THOMAS:

Q. In your study? Isn't that what --

A. I meant I didn't use the stains he used. I re-stained on stain slides. Maybe even cut the blocks.

Q. So is it your testimony that all of the information that you submitted to the journals was unrelated to your medical-legal work?

A. No. It's not unrelated because some samples came for medical-legal purposes.

Q. And for which you were paid to analyze by plaintiff's counsel, correct?

A. To provide reports.

Q. And what percentage of the cases that you report in the study were cases for which you were compensated by plaintiff's counsel?

MR. ORENT: Objection.

THE WITNESS: The study was not compensated by anyone. I did it on my own time, during my own time, and I don't know why you're saying that.

The percentage of cases which came through medical-legal litigation process is

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indicated in the paper.
BY MR. THOMAS:
Q. Okay. We'll get to that in a minute.
In the last year you've traveled and made presentations around the world on the research that you've done?
A. Yes, I did.
Q. Who has funded that work?
A. Pretty much I did.
Q. Did anybody subsidize your trips?
A. No, I mean, we have a specific portion of our salary from St. Michael's Hospital which is dedicated for presentations. But it's within my salary, it's more or less a way of getting it through a different tax bracket because it's money spent for -- it's within my contract.
Q. Did you receive any funds from plaintiff's counsel for your presentations in the last year?
A. Never.
Q. The articles that you had worked on --
A. The full answer would be I paid for all the trips and I never received any money

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for making presentations or publishing the papers.
Q. Okay. Let's go back to page 83. 83 again is the mesh fiber that you looked at under light microscopy 40 minutes to an hour after it was removed and before it was stored in formalin, correct?
A. That is correct.
Q. Where is that fiber today?
A. It's embedded in formalin. The specimen went into formalin -- sorry. The specimen went to formalin and now it's embedded in paraffin.
Q. Why is it in paraffin?
A. To take histological section.
Q. Have you taken histological sections of it yet? Have you taken histological sections of this mesh fiber yet?
A. Yes, I did.
Q. Are those reported anywhere?
A. What do you mean? This was St. Michael's Hospital patient. I described it, and I reported whatever I saw in the microscope.
Q. Okay.
A. It's not within the litigation process. It's a patient outside of litigation and the only way this picture made it into this report

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because it was in a publication.
Q. Did you obtain permission from the patient to do that?
A. For using the -- we have a standard protocol for research. We use material for research purpose and I had REB approval.
Q. Did you obtain permission from the patient to use this image?
A. As I said, each person who enters the hospital, academic hospital, St. Michael's Hospital, signs agreements or release form and it's covered by blanket research regulations.
Q. Does the patient know that her mesh fiber was featured in a publication?
A. No, I didn't tell her specifically to the patient.
Q. Okay. So the entirety of the excised mesh was then placed in paraffin?
A. I believe so.
Q. Is there any remaining of the mesh explant that was not put in paraffin?
A. I don't think so. It depends. If it's a large piece, which I don't suspect it is, there are some remnants which are stored in formalin. In this case, probably everything went

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to paraffin.
Q. So there still exists some mesh material in paraffin that could be available for analysis; fair?
MR. ORENT: Objection.
THE WITNESS: For histology?
BY MR. THOMAS:
Q. Yes.
A. Yes.
Q. And have you prepared histological slides of the mesh fibers that are contained on page 83 of your report?
A. Yes.
MR. ORENT: Objection.
BY MR. THOMAS:
Q. As I understand it, they are not part of your report in this case, true?
A. No. As I said, this patient has nothing to do with this report. The only mechanism that this paper appeared in this report because it was in peer-reviewed publication, that's it. Why are we talking about this patient? I don't understand.
Q. And if I wanted you to produce the paraffin with the remaining mesh and the slides

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that you have for this mesh, which is depicted on 83, would you do that for me?

MR. ORENT: Objection. I think you need to deal with the hospital and privacy laws of Canada. I don't think Dr. Iakovlev owns that property, nor --

MR. THOMAS: If he's not going to do it, that's all I want to know.

THE WITNESS: No, I will not do that. As I said, the paper is published. It's public, that is why it made it into this report. Everything which belong to St. Michael's and individual patients outside of litigation has nothing to do with this report.

BY MR. THOMAS:

Q. Did you wait until it was published before you used it in the report?

A. Yes, I did. I mean, it was published by the time I produced the report.

Q. Okay. Did you use it in any other report prior to the time that it was published in the journal?

A. I don't think so.

Q. That would have been inappropriate?

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A. Before it was published, or accepted -- it depends. It's my research project and I'm covered by REB.

So if it's within my research and knowledge it would be appropriate because I conduct research, that's information I extract during my research.

Q. So if you used it in a report against Ethicon prior to the time that it was published in the journal, that's okay, because it's a product of your independent research under the REB; is that correct?

A. Yes.

(Reporter sought clarification.)

A. Research Ethics Board.

Q. Is the Research Ethics Board the Canadian equivalent of the American Institutional Review Board; do you know?

A. No, no.

Q. What's the difference?

A. Ethics board is individual for specific institutions. Each institution has their specific research ethics board.

Q. What does the REB do?

A. They review your application.

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They see if there can be any harm to the patients, then they approve your methodology.

Q. And do you have a written document from the REB that approves your mesh research work?

A. Yes.

Q. Is there more than one that you have from there?

A. There was renewal.

Q. Did you submit an application to them for this REB approval?

A. Yes, of course.

Q. And you have that application still?

A. Yes, I should.

Q. What other documents did you have in your possession related to your request for, or their approval of your research in meshes?

A. Nothing. Just application and their approval letter.

Q. Did you have to appear before the REB to represent on your research?

A. No, it's a simple, it is a very simple project. I don't do anything to the patient. I don't do anything specific.

I do exactly what I do every day, so it

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was straightforward. It couldn't be any hard, just examining histologically.

Q. Let's take a break.

-- RECESS AT 10:19 --

-- UPON RESUMING AT 10:26 --

BY MR. THOMAS:

Q. Doctor, going back to the images on page 83 of your report, did you write a pathology report of your findings for your review of the histology?

A. Probably I did. Maybe I haven't completed it yet. With the meshes, I'm slow, so I could have completed the report, could have not. I don't remember now.

Q. What's your practice for doing a pathology report for a patient in the hospital who is not involved in medical-legal? Do you turn that around pretty quickly?

A. What do you mean is not involved in medical-legal?

Q. I thought you told me this was not a medical-legal case, this mesh that's on page 83 of your report?

A. That's correct.

Q. So, have you done a pathology

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report for this patient based on your review of the histology of her mesh?

A. Doesn't matter medical-legal or not medical-legal, when I collect mesh specimens because my work is done so slow, I think and it takes me time. It has nothing to do with medical-legal or not. The difference is mesh versus no mesh.

Q. Have you prepared any -- have you dictated anything related to the histology from the mesh ex-plant that's depicted on page 83 of your report?

MR. ORENT: Objection.

THE WITNESS: I don't remember.

BY MR. THOMAS:

Q. Have you written anything about your review of the histology from the explanted mesh that's based on page 83 of your report?

MR. ORENT: Objection.

THE WITNESS: As I said, I don't remember. I've written something, because there was a gross description at least there at the beginning of the report. Maybe it's signed out, I don't remember now. I use exactly the same format for all mesh specimens litigation, non litigation.

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BY MR. THOMAS:

Q. I understand that.

A. And because there are so many items I'm checking it takes me time and I don't want to do it in a rush.

With cancer cases it is a different story. I rush, I try to make sure diagnostic process is not involved. In this case the mesh is out already so there is no pressure.

Q. So to your knowledge, you don't know whether the doctor or the patient had the benefit of your pathological review of the histology, correct?

A. I think I described it for the physician.

Q. How did you describe it to her? In writing or voicemail or person to person?

A. I don't remember now. I'm not sure where we're going with this, this is confidential, and I'm not comfortable getting into confidential information of a St. Michael's Hospital patient.

The paper has been published and the picture made it in the report after the publication was peer reviewed and accepted.

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Now we're getting into completely different area and I said I'm not getting comfortable in getting into confidential information of a St. Michael's patient.

Q. I'm trying to figure out whether anything in writing exists to your knowledge that describes the findings you made based upon histological review of this explanted mesh.

MR. ORENT: I think he's answered those questions. I think he's gone far beyond his comfort level. Let's move on.

MR. THOMAS: Are you instructing him not to answer?

MR. ORENT: I'm not. However, if he believes that he's confined by Canada's confidentiality laws it's up to him in terms of his knowledge, and what he can share as a doctor over a patient who is not at issue in this lawsuit and not put their medicals at issue.

THE WITNESS: As I said, I'm not comfortable getting into further details. I think it's inappropriate. This picture appeared in the report because it was published.

BY MR. THOMAS:

Q. Doctor, on page 8 through 11 of

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your report, you have a section titled "Polypropylene Degradation and Review of Ethicon's Internal Documents"?

A. That is correct.

Q. How did you determine what documents to review from Ethicon?

A. I asked to send me anything which was available pertinent to polypropylene degradation, specifically if Ethicon scientists performed testing using similar technology and methodology, histology mainly.

Q. Did you rely on counsel to provide to you the documents that you reviewed?

A. Yes.

Q. Did you produce for us on Exhibit 4 all of the documents that you reviewed?

A. Yes, I did.

Q. Were there other documents that plaintiff's counsel supplied to you that you did not include on Exhibit 4?

A. Not to the best of my knowledge.

Q. All right. You also refer to deposition testimony of Thomas Barbolt?

A. Yes.

Q. Is Dr. Barbolt's deposition on

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Exhibit 4?
A. Yes, it is.
Q. Do you remember how many days his deposition was?
A. I think there were two days.
Q. Did you read the whole thing?
A. I read most of the deposition. Skimmed, I mean it's really long document.
Q. Do you recall what his job was at Ethicon?
A. I don't recall now.
Q. Do you know what his training was?
A. No.
Q. Do you know what kind of testing Dr. Barbolt conducted while he was at Ethicon?
A. I don't remember now.
Q. Do you know whether he conducted any animal testing of mesh?
A. I saw documents of animal testing, many documents. If he was part of all of them or some of them, I don't remember.
Q. Do you know whether he conducted any tissue reaction studies?
A. I don't remember that, no.
Q. Do you know whether Dr. Barbolt

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compiled and reviewed testing on Prolene polypropylene from the 1960s to the present?
A. As I said, there were many documents and it's hard for me to remember now.
Q. Do you know -- strike that. Is it fair to understand that to the extent Dr. Barbolt presented any testing in his depositions you have not reviewed that testing?
MR. ORENT: Objection.
THE WITNESS: As I said, I was asking counsel to provide specific information, specific topics. So they provided this information and I received a number of documents.
I specifically didn't even check whoever signed this, who were the names.
BY MR. THOMAS:
Q. Did you review any of the testing Dr. Barbolt reviewed in his deposition?
A. As I said --
MR. ORENT: Objection.
THE WITNESS: I don't remember the names. The only reason I remember his name because it was the only deposition I had specifically for that specific subject.

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BY MR. THOMAS:
Q. What testing do you recall reviewing as a part of your review of the Ethicon documents in the case?
A. As I said, I was focused mainly on histological examination but I also skimmed through the testing which was done using scanning electron microscopy and just regular light microscopy.
Q. Did you have see any histological examination of what was described as cracked polypropylene sutures?
A. Yes.
Q. And what did you find in your review of the histological examination?
A. I was really surprised. They found exactly what I found 30 years before I did. I did it independently; I didn't have those documents before. So I thought I was Columbus, but I guess I wasn't.
Q. And you say they found exactly what you found?
A. Yes, exactly the same. Even arrows were so much like mine.
Q. What was it that they found which was exactly what you found?

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A. There is a degradation bark and it retains histological dyes, and it also retains the granules of blue fibers. And they also used polarized light.
I think you asked me earlier in the deposition who was using polarized light before. Your scientists were.
Q. Is it your opinion that Ethicon conclusively found exactly what you found?
A. Yes.
Q. And that's based on the documents that have been provided to you?
A. Yes.
Q. Did you see any histological examination of the sutures that analyze to the extent to which it created any risk of harm to patients?
A. I don't think I understand your question.
Q. What don't you understand about it?
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Let me start over again. During the course of your review of Ethicon documents, did

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you review any documents where Ethicon scientists reviewed histological slides of tissue samples containing mesh that was described as having cracks?

A. Yes, I did.

Q. And do you recall what the tissue reaction was that they described in those samples?

A. Yes, I do.

Q. And what is that?

A. It is the same thing which I saw, fibrosis foreign body reaction formation.

Q. Do you know how the description they found in their documents compares to what the tissue reaction as described for Prolene sutures at the time that it was approved by the FDA in 1969?

MR. ORENT: Objection.

THE WITNESS: The documents I reviewed they were dated in '80s.

BY MR. THOMAS:

Q. I understand that.

A. They had exactly the same description as earlier papers or papers after that. So I don't think there is any difference in any of the descriptions.

Q. Okay.

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A. Either at time of filing of the FDA application or after, it's all the same.

Q. And the findings that they found in the '80s and the findings that they found earlier, and the findings that they reported later are just the same as yours are?

A. Pretty much.

Q. Okay. You say on page 9 of your report at the end of the first paragraph:

"An important conclusion should be made that if chemical and physical properties have material change while it is in the body, it should not be used for permanent applications and for anatomical sites from which the devices cannot be safely removed."

Did I read that correctly?

A. Yes, you did.

Q. Does St. Michael's use Prolene sutures?

A. Yes, I understand they do.

Q. Does St. Michael's use Prolene hernia mesh?

MR. ORENT: Objection.

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THE WITNESS: I see it removed. Probably it's used for hernia mesh as well. Prolene or Marlex, I'm not sure. There are newer meshes coming on the market.

BY MR. THOMAS:

Q. Does St. Michael's use Prolene polypropylene mesh for the treatment of stress urinary incontinence in TVT and TVT-O?

MR. ORENT: Objection.

THE WITNESS: I don't think so.

BY MR. THOMAS:

Q. Do you know?

A. Maybe in the past. Right now I just receive them when they're removed.

They've been using them before. I don't know if they still using it right now.

Q. Have you told St. Michael's to stop using Prolene polypropylene sutures?

A. Not sutures. I talk to gynecologist. I show them what my research found, what I found, let them know, what's, what's my opinion about this.

Q. Who did you talk to at St. Michael's about that?

A. Our gynecologist.

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Q. I'm sorry?

A. Our gynecologist.

Q. And who is that?

A. I don't think I can go there. Again, I'm not comfortable getting into specific information which is not relevant to my report.

Q. What did you tell that person?

A. I shared my research, what I shared in my papers.

Q. Did you tell them that St. Michael's should not use Prolene polypropylene?

A. I'm not making any guidelines. I'm not a regulating body. As a researcher I can share my opinion, my findings, with colleagues. And that's what I do in my publications and that's what I did in my personal conversations and personal contacts with St. Michael's physicians.

Q. When did you have those conversations?

A. Throughout. I've been involved in these meshes for the last year, maybe over a year, I don't remember now. First it was hernia surgeons, then gynecologists.

Q. So you've spoken to hernia surgeons at St. Michael's about the use of

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polypropylene mesh?
A. That's how it came, it came through hernia surgeons. The whole research project came through hernia surgeons.
Q. Do you know whether hernia surgeons at St. Michael's are still using polypropylene mesh?
A. Probably they do. But not all of them. Some of them do, some of them don't.
Q. Do you know whether St. Michael's continues to use polypropylene mesh for the treatment of stress urinary incontinence?
A. As I said, I know they've used it. I don't know if they're still using it right now as we speak.
Q. Did you ever tell them as a scientist and pathologist that they should stop using Prolene polypropylene mesh because it was harming their patients?
MR. ORENT: Objection.
THE WITNESS: I described pathological findings and I disclosed everything I found in the specimens which were coming to me as part of St. Michael's Hospital and what I found during the course of my research. Yes, I did disclose all of

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this.
They are independent practitioners. They collect information from peer-reviewed studies. They see the evidence which is published. I'm one piece of the puzzle, one piece of the information.
They make their own decision. They're licensed physicians and there are regulating bodies which give guidelines.
Again, they are free to use my guidelines in my research or anything else and advise their patients what is the best course and what can be complications.
BY MR. THOMAS:
Q. Who was the person at St. Michael's who makes the decision whether to use polypropylene mesh?
A. Each individual physician makes own decisions after discussion with the patient. That's my understanding.
I don't think there is any guiding body in specific hospital which can stop physicians from using specific device.
Q. When you said you went to the gynecologist, there's more than one gynecologist at

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St. Michael's, isn't there?
A. Yes, but not all of them are dealing with stress urinary incontinence. There is a degree of specialization. Some of them do it, sometimes some people specialize more in the field.
Q. There's more than one hernia surgeon, isn't there?
A. Yes, correct.
Q. Is there someone over both of those specialties that can determine that the hospital should not use polypropylene sutures or mesh?
A. I don't know if it can be done.
Q. Have you ever made an effort to do that?
A. To stop them?
Q. (Nods).
A. As I said, I don't know if it can be done.
Q. Have you ever made an effort to stop St. Michael's Hospital from using Prolene sutures or Prolene mesh other than the conversations you had with a gynecologist and a hernia surgeon?
A. No.

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Q. Thank you.
What did Dr. Barbolt say about the clinical significance, if any, of surface cracks on polypropylene implanted in the dog study?
A. I don't remember now.
Q. What did Dr. Barbolt say about the molecular weight of the Prolene sutures implanted in the dog study after seven years?
A. I don't remember now.
Q. What did he say about the -- strike that. What did Dr. Barbolt say about the physical properties of the Prolene sutures implanted in the dogs after seven years?
MR. ORENT: Objection.
THE WITNESS: I don't remember now.
BY MR. THOMAS:
Q. Page 11 of your report. You talk about effect on the tissue, we're talking about pain -- sorry, I'm on the wrong page.
It's on page 12, I'm sorry.
A. Okay.
Q. Page 12, it says:
"It is important to note that in hernia surgery, chronic pain after mesh repair is a growing

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problem. Prophylactic neurectomy is offered as a method to reduce incidence of pain after mesh repair."

What is a prophylactic neurectomy?

A. When you cut the nerves before you put the mesh in anticipating the mesh is going to cause pain.

Q. When you say cut the nerve, what kind of nerve are you going to cut in the hernia surgery?

A. There are three main nerves branches: Genitofemoral, inguinal, um, some names, um...

Q. Any other nerves as a part of the hernia surgery?

A. There are three branches, which can be identified visually. They are thicker trunks. There is a variability between people, but they're called triple neurectomy because in most people there will be three branches supplying innervation to the area.

Q. So tell me what is done and why it's done in hernia surgery with prophylactic neuroectomy?

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A. It depends. There's different techniques. Either the branches can be cut in the area, so there will be three branches identified and transected, buried in muscle. The stumps will be buried in muscle.

It could be also arthroscopic techniques when they go and try and cut the nerve trunks closer to the spinal cord.

Then I'm not sure if it will be three branches, because if you go proximally it will be less branches, they will all merge into larger trunks. So you cannot call it triple neurectomy at that level.

But the basic rule, we try to identify supply innervation, either larger trunk or smaller branches, transect them and bury the stump in the muscles, so it doesn't form traumatic neuroma.

It's done because you want to denervate the area where you anticipate the mesh is going to cause pain.

Q. Why is it important to note the prophylactic neurectomy in your report?

A. Because when chronic pain due to mesh occurs, going back into the scarred area, obstructed by the mesh, proved to be hard.

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So historically, first there were meshes put in, and then more meshes put in, and then more patients started coming back as chronic pain, taking the mesh out was difficult, there was large defect.

So somebody came up with the idea, let's leave the mesh in but try to denervate the area, either bury the nerves with some chemicals like alcohol, or put nerve blocks, which was an effective strategy.

You anesthetize the area, so the nerve doesn't work for few weeks, and then the pain would be gone.

And then somebody came up with this idea of more permanent denervation, when the area is anesthetized by cutting the nerve.

And then first surgeons try to do neurectomy or transection of the nerve after mesh repair, and after some experience they figure out it's really hard to do to find the nerves from the old scarred area.

So somebody offered, okay, if we anticipate the pain developing from mesh, let's cut the nerve before, when the area is clean and there are no scarring or mesh in the area.

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Q. Is that an accepted surgical technique to do a nerve neurectomy prior to mesh implantation?

A. Yes, it is. It's offered, it's published and there are results.

Q. Is that a common occurrence with mesh implantation?

MR. ORENT: Objection. Vague.

THE WITNESS: Depends on the surgeons. Some surgeons believe in this and they do it. Depends probably on the group of surgeons' practice habits.

BY MR. THOMAS:

Q. Right above that section on the prophylactic neurectomy, you discuss the mesh scar complex and its "interlocking and compartmentalizing nature". What is the interlocking and compartmentalizing nature of the mesh scar complex?

A. So if we look at the mesh, mesh is a structure, three-dimensional structure made out of mesh fibers or mesh filaments.

So filament of fiber, circles around, loops around, and then it forms in pores, and in these tissues. And each pore has 360 degrees of

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surrounding fibers, that's why it is a pore.
So it becomes a compartment. An area which is surrounded by something or a physical structure with volume inside, that is a compartment. So the mesh introduces all these micro compartments.
Q. There aren't walls around each of these compartments, are there?
A. Yes, there are. Fibers, mesh fibers, they form the walls of this compartment.
Q. But they don't totally encapsulate -- strike that.
The compartment though, has an opening on either side much like a screen, correct?
A. Yeah, more like a screen or a tube. To a degree, because mesh is not completely flat, it's a more of a three-dimensional. If you go with microscopic level, it's three-dimensional.
So I would compare it with each pore as a very complex irregular tube, more or less.
Q. My point is, instead of a compartment it is a tube with openings on either side?
A. A compartment is a tube. All compartments in human body are tubes.

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Q. That has an opening on either side?
A. Yes, that's how they are in the body. If we talk about tunnel syndromes in the hand or in the chest, all these compartments form a tube.
And the tube lets nerves and blood vessels through and if compartment syndrome occurs, it compromises the nerves in the vessel, in the tube-like structure.
Q. Doctor, in your report you discussed the concept of mesh stiffening?
A. Yes, I did.
Q. Please tell me how mesh stiffens?
A. Immediately after placement, it can fold and curve. So two layers or three layers of mesh is different than one layer. So this is initial step, if it folds or curls or wrinkles immediately after placement.
Then next step which will increase stiffness of the structure is scar encapsulation. So scar immobilizes the fibers in the structures so they can not move inside the elasticity of the meshes, mainly because of the bending ability of the fibers and movement within the structure.

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When it's used with scar it cannot so that is lost. When it's incorporated in scar tissue, the movement and bendability of fibers is limited.
Q. Let me ask you a question here; I don't mean to interrupt you. Is folding or curling a necessary part of mesh stiffening?
A. No. It's one of the processes which increases mesh stiffness if you compare it with the flat product.
Q. So you can have, as far as you're concerned, mesh stiffening if the mesh does not fold or curl?
A. Then other mechanisms will set in.
Q. But the first one deals with folding, curling and then the scar that you just described?
A. Yes.
Q. I didn't mean to interrupt you. Is there anything else you wanted to say about that mechanism?
A. And then slowly over the years, the degradation layer will start building up and we know it's brittle. Like any other plastic, we see over time it starts cracking. It becomes harder

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and less flexible and it breaks.
Q. The degradation layer you described is four to five microns?
A. It depends. It depends how long it's been in the body.
Q. Is four to five microns about the largest you've seen?
A. No, I've seen up to seven or eight. Depends on the type of mesh, I guess --
Q. Well, Prolene polypropylene, what is the largest you've seen?
A. It's hard to say because it's for -- currently that mesh is -- 80 percent of the time I don't actually know what the product is.
Q. 80 percent of the time you don't know what the product is?
A. Yes.
Q. And the reason why I ask is, in all the reports I've seen, I've never seen you give an opinion that is greater than five microns to a Prolene mesh?
A. That's just happened with any litigation process, but I have over 300 meshes in my office.
I'm just telling you the thickest bark

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as far as I remember was up to seven, probably just over seven microns thick.

And I think it was a hernia mesh and for hernia meshes, when they've been in the body for like 12 or 14 years, it's very difficult to trace what type of mesh was put in.

Q. Your best recollection insofar as you're dealing with Prolene mesh for the treatment of stress urinary incontinence, the largest you've seen is five microns, correct?

MR. ORENT: Objection.

THE WITNESS: Probably six, I don't remember now.

BY MR. THOMAS:

Q. This bark, as you've described it, by definition is cracking?

A. Yes.

Q. And when you get past the bark layer the interior of the polypropylene as best as you can tell is unaffected?

A. Yes.

Q. Okay.

A. The core of the fibers remains, at least, the same by my methods.

Q. And by your methods, as far as you

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can tell, past the five microns or so, the physical properties of the polypropylene remain the same, true?

MR. ORENT: Objection.

THE WITNESS: By my methods, yes.

BY MR. THOMAS:

Q. Have you described -- you've described two ways that you believe that mesh becomes stiff.

Are there any other ways that you believe mesh becomes stiff in the body?

A. Three. So multi layering, scar encapsulation and then degradation. No, I don't know any other mechanism for stiffening.

Q. And the way that you're able to identify multi layering is when you analyze the mesh after it's been sent to you in formalin from the surgeon, correct?

A. As I said, sometimes I receive meshes fresh in saline or not just -- and I see it's folded already.

Q. The only polypropylene meshes that you've given us, other than the one that you've given us limited information about, come to you in formalin, correct?

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MR. ORENT: Objection.

THE WITNESS: For litigation cases? Meshes come in formalin, that is correct. But in St. Michael's Hospital, when they receive mesh, as I mentioned, everybody knows I'm the mesh guy. They call me when they receive a mesh, sometimes I receive them fresh.

BY MR. THOMAS:

Q. Do you have any documents, images or any other information about meshes that you've received fresh, without formalin, that show folding or curling?

MR. ORENT: Objection to form.

THE WITNESS: I describe them when I receive them. But again, we're going to the St. Michael's Hospital patients and I don't want to go there. I'm not comfortable discussing this confidential information.

BY MR. THOMAS:

Q. Okay.

A. Probably took some pictures at some time.

Q. You have not produced those pictures to us?

A. They're not in the report.

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They're confidential information and I took them because in the course of my work as a pathologist at St. Michael's.

Q. Do you have any information about the incidents of folding or curling in mesh implanted -- in Prolene mesh implanted for the treatment of stress urinary incontinence?

A. For stress urinary incontinence, the degree of curling is visible in most of the cases.

Q. More than half?

A. I would say more than half. Again, it depends. Sometimes one piece is curled, the other one is completely flat.

Q. And again, these are cases where you've received the mesh in formalin?

A. Yes. But I mean we're talking about curling, not curling on the whole specimen. We're talking about curling as it sits in scar tissue.

So whatever curling I'm assessing as is significant is on that, that which can -- which is immobilized by scar tissue.

So I'm not talking about curling which occurs secondary to fixation. I'm talking about

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curling which occurred in the body. I'm able to distinguish between one and the other.

Q. How?

A. I just said. If it's curled and it's completely surrounded, integrated in scar tissue in curled shape, it occurred in the body.

If the entire specimen is curled together with scar, that could have been an artifact. So I immediately disregard the shape or the formation which occurred as an artifact.

Q. Let's go to page 19 of your report, please.

A. Um-hum.

Q. I'm going to refer you back to page 14, because I think that that's the commentary that you have on that. So you've got 19, which is the images, and page 14 is the text.

A. Yes.

Q. Okay. As you look at page 19, Figure Set 1a is described as:

"A foreign body inflammatory reaction H&E, 40X images consolidated cases."

What are you showing here?

A. Foreign body type inflammatory

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reaction.

Q. Is there anything unusual about this foreign body reaction?

A. What do you mean unusual?

Q. Is there anything remarkable about it? There's a foreign body reaction anytime you have an implant, correct?

A. Then usually it's not normal tissue. Normally there shouldn't be any inflammation in the tissue.

Q. Okay. And so would there be inflammation regardless of what kind of foreign body is placed in there?

A. Yes, because having a foreign body in the body is not normal thing.

Q. And so is it fair to say that Figure Set 1a describes a typical foreign body reaction to implanted materials?

MR. ORENT: Objection.

THE WITNESS: I wouldn't say typical, although you can use that word. I would say non-specific reaction to a foreign body. The body is trying to destroy the foreign body because it's a noxious stimulus, a noxious or damaging object.

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BY MR. THOMAS:

Q. The images on the left show that the polypropylene was removed as part of the microtoming process; correct?

A. Could you repeat that question.

Q. I'm looking at the figures on the left, which show the white images, compared to the right, which show the yellow.

And on the left it shows that the polypropylene that used to be where the white is has been removed as a part of the microtoming process; correct?

A. No, actually, there might be all of them present there. They're just clear; polypropylene is clear. If it is not degraded, it's completely clear.

If the fibers were blue fibers, they would be visible. If it's clear fiber they would not.

So technically, looking at these images, we cannot say which hole is the actual MTM, and which sort of appear in holes, still contain polypropylene. You would need polarized light to see that.

Q. So what can you tell me about the

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part of the mesh that we're seeing in Figure 1a?

A. Specifically, I don't -- do you want me to discuss a specific feature?

Q. For example, you don't have a clean cut where you're looking at a perfectly round portion of the mesh, correct?

MR. ORENT: Objection to form, to the use of the term "clean cut".

THE WITNESS: Some of them are closer to perpendicular orientation. Some of them are angled.

BY MR. THOMAS:

Q. Okay. For example, when you have a microtoming process and you pull the knife across the histological slide, sometimes you will create an artifact by pulling the tissue away from the polypropylene, correct?

A. Yes, because polypropylene is harder than tissue, you can damage tissue during cutting.

Q. And you can't tell if you look at set 1a whether the polypropylene is there or not; true?

A. Yes, that's true.

Q. You can't tell by looking at the

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figures in set 1a whether those are the actual size of the hole that was occupied by the polypropylene, and whether that is an artifact from microtoming?

A. That I can tell you because artifact from microtoming looks completely different. These are holes from fibers.

Q. Completely?

A. For these specific holes?

Q. How can you tell the difference?

A. Well, you have to work as I pathologist for so many years and then you can tell.

But generally, how we go for that specific feature, it would be shape, rounded shape, oblique, assuming, if we look at this image here -- if you want me to point, circle.

Q. I'll give you a red pen -- let's give you a blue pen. That will show up better.

A. Assuming if we see this tissue, this specific, this is displaced. So when the fiber was not cut, it probably had different position, different orientation. Because it's misplaced, it doesn't completely circle here.

Q. Is that an artifact from the microtoming process?

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A. To a degree.

Q. Okay.

A. Now, see this empty space here?

Q. Mark that A. Mark the first one A, and the next one B, so the record is clear what you've just done.

A. (Witness complies).

Q. This one will be A. That's the one you've discussed first. The other one you're discussing now is B.

A. So this circle labelled A moved during microtomy. It was within the fibers and now it moved, it changed position slightly.

The area B appears empty, but it was occupied in vivo, and this is an artifact. Another artifact here is artifact C, which is tissue retraction. Now, if we --

Q. And those are all caused by the microtoming process?

A. No. Different combination of factors which cause all of this.

Now, if we look at the entire opening marked as D, is perfect round shape, no tissue is displaced. So this would be as close as it gets to the area which is occupied by a cross-section of

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the mesh fiber.

Q. Okay. Let's go now to the next page, page 20. Anything else remarkable about that page, page 19?

A. It depends what you want me to describe.

Q. Well, I've seen you testify before. And you put these images up on the screen and you tell the jury what you think is remarkable about them?

A. Do you want me to go through this description?

Q. Do you have anything other than a foreign body reaction, as depicted in the tissue, is there anything other than that that's remarkable about the images on 19?

A. This picture is actually good in terms of it shows this layering.

So the fibers are surrounded by this dense foreign body type inflammation, and then the inflammation is actually encapsulated by dense scar on the outside, so this very dense pink area is a scar. So it goes on the outside of the inflammation.

And then beyond the scar plate, here is

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the transition into normal lighter tissue not as densely scarred or densely collagenized.

So this picture is a good example of showing this multilayering, sort of onion skin around the mesh fibers.

Q. Anything else?

A. No.

Q. Let's go to page 20 now.

A. Now, I have the mark coming through. Should I use a pen?

Q. We'll do that next time, we'll take that away.

Now on page 20, again, this is an image from the consolidated cases?

A. That's correct.

Q. And as you look in the top on 1b, you see blue. And that is polypropylene mesh.

A. Yeah, that's a cross-section of a blue polypropylene fiber.

Q. And it looks like it's been folded as a part of the microtoming process; is that fair?

A. It's not microtoming process; it folds, curls. Polypropylene just tends to curl.

Q. But this is a four-micron thick slice of polypropylene, correct?

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A. Then it curls up like this. Some of them just stay flat. Some of them curl up.

Q. But this is an artifact of the sample preparation process?

A. Curling? Yes.

Q. So the curling of the blue polypropylene in set 1b on page 20 is an artifact of the sample preparation process?

A. That's correct.

Q. All right?

A. The exact shape of that slice is better to be estimated by the tissue which surrounds it because tissue didn't curl, didn't move much. There is more movement of the polypropylene slices.

Q. What does that mean? I don't understand.

A. Well, see, when the tissue is cut it doesn't curl, it doesn't wrinkle most of the time because of the technology of the slides and knives. Everything was designed to keep it flat.

So over the years, over the hundred years we learned how to keep it flat. With polypropylene, because it is a different material, doesn't stick. The histological slides don't hold

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it as well so it's not firmly attached.

So, when it's cut initially, it may stay flat. But then after drying and some chemical treatment, starts curling up, while tissue stays flat.

Q. Okay.

A. Curling up or moving, I mean curls up, lifts up, and then starts floating around.

Q. What are you going to say at trial about Figure Set 1b on page 20?

A. Just an example of foreign body type inflammatory reaction.

Q. Okay. Let's go to page 21.

A. Yes.

Q. Page 21 is Figure Set 1c:

"Foreign body inflammatory reaction, H&E 40X, image of additional TVT cases."

Now, I think you told us before that these are previous TVT and TVT-O cases?

A. Yes.

Q. Do you know whether this is a TVT or a TVT-O?

A. No.

Q. Can you tell me today whether this

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slide comes from the set of 22 patients that you received from Dr. Kreutzer?

MR. ORENT: Objection.

THE WITNESS: My recollection is it was later, one of the later cases.

BY MR. THOMAS:

Q. Do you know which one it is?

A. I can probably trace it but...

Q. Is it a medical-legal case?

A. I think so, but again it would be hard for me -- just what I recall, it is a TVT that I kept track quite well, TVT or TVT-O.

Q. If I asked you to, could you tell me where it came from?

A. I can make an effort to figure it out.

Q. Okay.

A. If I can't, I can't.

Q. I'm going to want to know where all these came from. That's what we asked for in advance and I understand we don't have it today?

A. I never had the purpose to trace individual cases unless it's for a specific -- the report is prepared for a specific patient.

Q. Okay.

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A. Because of it wasn't my purpose. My purpose was to collect information and photographs for TVT or TVT-O as device. That's why I have difficulty tracing all of them back. Some of them can be traced; some of them cannot.

Q. If you look at Figure Set 1c, top left, again, you see the blue polypropylene, correct?

A. Yes, I do. And the other hole above it may still contain polypropylene but it's clear because the way it's done two fibers are combined together.

One filament is blue, one filament is clear. And they go through the knitting product together, this pair.

Q. Does the fact that the hole that you just identified above the presence of blue polypropylene has an irregular shape, does that impact your opinion as to whether the polypropylene is present or not?

A. Not irregular. It's more regular curvilinear shape, and there is inflammation around it, so there are several features which tell me that this is space where polypropylene either still is or used to be.

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If I had polarized light or if I had microscope right now and it would be in the microscope, I could flip polarized light and see.

Q. Now, is that tissue that is in that large white area above the polypropylene?

A. It is a small fragment of tissue.

Q. Is that part of a microtoming artifact?

MR. ORENT: Objection.

THE WITNESS: Microtomy or processing, it's hard to say, but it's an artifact. It's displaced.

BY MR. THOMAS:

Q. As you look down to the piece of polypropylene in set 1c, on the top of that blue portion it appears to be some tissue?

A. Yes.

Q. And that tissue looks to fit right into the tissue above it?

A. That's correct.

Q. So that's pulled away from the tissue as a part of the microtoming process, correct?

MR. ORENT: Objection.

THE WITNESS: You have good eyes.

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BY MR. THOMAS:

Q. Why don't I see any bark on that polypropylene?

A. Two reasons. Not enough resolution of the picture, and second, not in focus.

Q. And do you know how long this mesh was implanted in the person?

A. No, I don't remember.

Q. But you have those records?

A. Most likely. But again, some patient samples came without much records. Most of the samples I received had implantation dates.

Q. So what is remarkable about the slides in Figure Set 1c which you'll talk to the jury about?

A. It shows a blue fiber. It shows that some of the fibers are blue, but otherwise it shows exactly the same feature as before.

It's kind of onion skin mesh fiber covered by inflammation, and then outside of that everything is encapsulated in scar tissue.

Q. And the scar tissue would be reflected in your notations in the ones on the right?

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A. Yes, sometimes I do that.

Q. Okay. Anything else remarkable about the figures on page 21?

A. No.

Q. Let's go to page 22, Figure Set 2a. Again, this is images of additional TVT cases. And these would be cases that were not part of the consolidated group that you've just reviewed, correct?

A. That is correct.

Q. And can you tell me by looking at this whether it was part of the set of cases that you received from Dr. Kreutzer?

A. No, that was later case.

Q. How can you tell me that? How do you know that?

A. Quality of the picture. I see it was not taken with the camera that I had at the time that I received the, those specimens.

Q. Was this taken from an active medical-legal case involving Ethicon?

MR. ORENT: Objection to the form.

THE WITNESS: I don't remember. Most likely it is.

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BY MR. THOMAS:

Q. But you can't tell me today what it might be?

A. It's hard to say.

Q. And what is remarkable about the image in Figure Set 2a on page 22 for purposes of the jury?

A. Can I have a pen?

Q. I'll give you a blue pen.

A. Remember, earlier you asked me about why you cannot see bark? Now you can see the bark, so this is the bark. Right there.

Q. What you've indicated is on the left?

A. This is the bark right there. This is the bark right there.

Q. Now are you assuming for purposes of that statement that polypropylene is still present in that slide?

A. Well, degraded part of the polypropylene is still present for sure, because I can see it stained. If the core remains unlocked, there's a different question. In this area, most likely it is.

Q. You say most likely it is?

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A. Because this bark layer is free in the space, and doesn't happen that often. Because if it was free in this area, it would flow all the way. So the way it remains in the tissue it remains attached to tissue.

So the bark which is firmly attached to tissue like in this area is most likely detached. So there is no fiber core in this area. But in this specific area, I suspect the core of the fiber is still there.

Q. Let me do something so the record is clear.

You've made some arrows on Figure 2 A, on the upper image, and there's two arrows on the upper left-hand portion and you suggest that indicates bark -- you suggest that indicates bark, correct?

A. I didn't suggest. I just pointed where it is.

Q. Okay, fine. And then down in the lower right-hand corner, you've drawn several diagonal lines in addition to two arrows.

The two arrows indicate bark, as you understand it, and you believe that the diagonal lines represent polypropylene which is present in

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the slide, correct?

A. Most likely.

Q. Okay. Now, we requested that all of the slides that were used in your report be forwarded to our pathologist for their review.

Was this slide forwarded to them, to your knowledge?

MR. ORENT: Objection.

THE WITNESS: No, it's an additional case.

BY MR. THOMAS:

Q. Okay.

MR. ORENT: By the way, just for the record, we have not received any slides from your pathologist either and we have requested that repeatedly.

MR. THOMAS: We don't have any to give you. We're working from the same set of slides.

MR. ORENT: So you're using the plaintiff's stained slides --

MR. THOMAS: So far we have. We figure it's better off using one set of slides. And to the extent we make any, you will have them promptly.

THE WITNESS: If it was a litigation

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case, you have the report.

BY MR. THOMAS:

Q. Are you familiar with whole slide imaging?

A. Yes, I am.

Q. Do you do whole slide imaging of these cases?

A. Yes, I do.

Q. So you have --

A. Not for all of them. For some cases, especially the later ones.

Q. Okay. And who maintains your whole slide imaging equipment; who has that? St. Michael's?

A. Yes, St. Michael's. It's standard equipment.

Q. Do you have to pay St. Michael's for use of the whole slide imaging equipment?

A. No.

Q. Okay.

A. It's free for researchers.

Q. What kind of machine do they have?

A. Aperio.

Q. So, you could supply to us digital images of the slides that you have on whole slide

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imaging, correct?

A. As long as you're entitled to receive material or information about the case.

Q. Okay. What else is remarkable about Figure Set 2a on page 22?

A. Oh, it is a very nice example, again of this layering, onion skinning.

The mesh fibers are surrounded by halo of foreign body reaction and everything is encased in solid scar plate.

And then normal tissue is beyond the solid scar plate so it is a good example of how it happens.

Q. And in terms of -- you've told me that on the upper left of the area where you had the arrows, there's likely not polypropylene but in the lower right there likely is polypropylene?

A. Yes.

Q. How about in the white area to the right where you've written; can you tell whether polypropylene is present or not?

A. Not without polarized light.

MR. ORENT: Counsel, we've been going about another hour. Shall we take a short break?

MR. THOMAS: Good time, yes.

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-- RECESS AT 11:27 --
-- UPON RESUMING AT 11:44 --
BY MR. THOMAS:
Q. Doctor, going back to image 2a on page 22 of your report, you described this scar area in your testimony, and then showed how the scar then changed to normal tissue, correct?
A. That' is correct.
Q. How thick is the area between what you show to be the polypropylene mesh and the scar to the normal tissue? How thick is that area between the polypropylene and the normal tissue?
A. You mean in this specific image or in general?
Q. In this image.
A. It depends on which part of the mesh. The thinnest part is within the hundred microns. The thickest part can be as thick as couple of millimeters, if we measure the whole thing like this.
Q. And just for the record, when you say within a hundred microns, you're referring to the area on the left side of the lower image in the yellow, through the scar to the normal tissue. And when you're referring to the couple of millimeters,

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you were referring to normal tissue to normal tissue in between the two mesh fibers; is that fair?
MR. ORENT: Objection.
THE WITNESS: That's correct.
BY MR. THOMAS:
Q. And similarly, down below on the lower left, where you show the polypropylene mesh, you show scar and then you do show normal tissue; how far is it from the polypropylene to the normal tissue; how wide is the scar band?
A. The same, within 100 microns. Sometimes you have normal tissue pushing into the pores, sometimes not. Sometimes the scar plate is within a hundred microns -- I mean, the scar capsule. Sometimes it goes to the millimeters, three, four millimeters, it depends.
Q. Okay. Anything else remarkable about the images on page 22?
A. No, we discussed everything, I think.
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Let's go to page 23 please, Figure Set 2b. Let's talk about this a little bit.

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Where does this come from?
A. It came from, if I remember correctly, Edwards case. If I remember correctly.
Q. What is it about this that makes you think it's the Edwards case?
A. It is an old photograph.
Q. And in the top, on the right-hand side of the image, it looks like a piece of blue polypropylene that's displaced in its location; is that fair?
A. Slightly displaced, most of it sits right there, it was in vivo.
Q. The other blue pieces that appear there other than the -- why don't you just mark that with an "X" for me so it's clear what we're talking about.
A. (Witness complies).
Q. There are other blue pieces throughout that image, is that polypropylene or is that stain?
A. You mean the blue areas here?
Q. Yes.
A. Some of it is probably displaced polypropylene, it's hard to say because of the resolution. It could just be inflammation because

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there is a weird color coming into the pictures.
Q. If the blue that appears there is in fact displaced polypropylene, then that's part of the microtoming artifact; is that fair?
A. Yes, that's fair.
Q. All right.
A. Anywhere where cross-section of the fiber overlaps with tissue, is a displacement.
Q. All right. And you title this, "Fibrous Bridging and Scar Encapsulation". And it's four times power. What does this show?
A. All pores in this section of the mesh are filled with scar tissue. So normal tissue is beyond the scar plate, and all the pores are in the spaces in between, and mesh walls are filled with scar tissue.
Q. Okay. The magnification of the image on the prior page is five times this magnification, correct?
A. About, yes.
Q. Okay. And can you tell me by looking at the image on page 23 in the cluster of four circles, how close it is from the polypropylene across the scar tissue to the normal tissue?

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A. In this area?
Q. Yes.
A. It would be within the 100 microns or so.
Q. Mark that -- good.
A. (Witness complies).
In this case, it's thicker, could be as thick as 200 microns.
Q. Okay.
A. It could be .2 millimeters, roughly.
Q. If you wanted to measure that on the slides that you have, can that be done?
A. With a eyepiece micrometer, yes.
Q. Anything else remarkable about Figure 2b other than showing the scar?
A. Fiber bridging, and completely encapsulating the entire structure of mesh pores that fill the scar tissue, and normal tissue is outside. This is the mesh scar complex, or mesh scar plate.
Q. As you look at this image, is this a complete slide?
A. No, there is tissue beyond slightly. And this end, I think is here on the

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next page, page 24.
Q. Okay. We'll come to that in a second.
A. That's my recollection.
Q. The figure on 2a, page 22, is obviously a smaller part of a bigger slide, correct?
A. That's correct.
Q. And you believe that the image on page 23 is also a smaller part of a bigger slide?
A. I think most of the mesh is here on the slide --
Q. Um-hum.
A. -- so there's not much mesh beyond.
Q. That's why I'm asking the question.
Does the image that's shown on page 23 represent the outer boundaries of the mesh in that slide?
A. I think so.
Q. Okay.
A. I think so, there's an edge of tissue here. Now, this exactly piece of this --
Q. You've now turned the page, you're on page 24. So you believe this is probably from

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the Edwards case, your best recollection?
A. Yes.
Q. And it's magnified ten times, and this is the one that is a magnification of the far right side of the image on page 23?
A. Likely at different level.
Q. What do you mean, a different slide?
A. Different slide, yes.
Q. Okay.
A. So it's the same piece, but cut little deeper.
Q. Now if you look on the top page of page 24, top image, on the right side there's a blue, that's again, displaced polypropylene?
A. Yes, this is displaced polypropylene. And this as well (indicating).
Q. Okay. And that's an artifact due to the microtoming process?
A. It could've done that, yes.
Q. And the description down below again is "fibrous bridging and scar encapsulation", does this image show anything in addition to what we've talked about in the prior slides?
A. This is a terminal pore.

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Q. Sorry?
A. This is a terminal pore of the mesh. So this is the edge of the mesh and the terminal pore contains normal non-scar tissue.
Q. When you say "terminal pore" that's the outside pore?
A. Yes, it is.
Q. So what is the significance of the terminal pore having normal tissue?
A. It just shows comparison. Pores which are not filled with scar tissue, and pores which are filled with scar tissue. So this specific pore contained normal scar tissue. So within that specific pore, there's no fibrous bridging.
Q. Is it fair to say every place we see the blue, we see displaced polypropylene?
A. Most of the time. It can be just a weird color of inflammation.
Q. Okay. Anything else remarkable about the slide on page 24?
A. No.
Q. Okay. Let's go to page 25.
A. Yes.
Q. This is cited to an article. Do

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you know off the top of your head what article that is?

A. On the safety of synthetic sling surgery, I believe.

Q. Are you able to tell me what slide that is, what plaintiff? Strike that.

Is that a medical-legal slide?

A. The picture comes from the same case, as you can see it's exactly the same.

Q. Okay. Is B part of A?

A. No, I don't believe so.

Q. Let's talk about A. And what does the "BF" mean?

A. "Bridging fibrosis".

Q. And the "AT"?

"Adipose tissue"?

A. Adipose tissue, yes.

Q. What is the significance of the adipose tissue?

A. It's a normal non-scar tissue.

Q. So what is the significance of including this slide in your report if it's the same thing that you had in the prior two slides?

A. It's a little bit different. Because, see, on the bottom, B, it shows scar

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tissue in a different stain.

Scar tissue may have some smooth muscle, when the scar tissue is being remodeled by myofibroblast. Myofibroblast can have smooth muscle. But once it's mature scar tissue, there is no contractile filament in the cells anymore, and it doesn't stain with smooth muscles stain.

But, normal tissue of vaginal wall contains smooth muscle. So here you can see that the fibers bridging, can be separated from normal tissue by using smooth muscle stain.

Q. And so the smooth muscle, or the normal tissue is represented by the brown?

A. Yes.

Q. And this is another representation of the fibrous bridging and scar encapsulations depicted in blue?

A. Yes.

Q. Is that the only significance of that stain?

A. Yes.

Q. Okay.

A. For this specific picture, yes, it is.

Q. All right. Are you able to tell

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me the magnification of that image?

A. Close to times four maybe -- because there's cropping and then the size was -- now it's hard to -- it's much larger than it appears in the publication. So I would say for this specific, it would be close to times four objective.

Q. If you go down here it says: "Scar encapsulating mesh in surrounding pre-existent normal adipose tissue and muscle tissues, a 2.5 image of histological sections." That means it's magnified 2.5 times.

A. It means that the objective you would use to produce this appearance in the microscope, this would be times 2.5.

Q. Okay. But the degree of magnification is different from that?

A. On this page?

Q. Yes.

A. Yes. Because it's cropped and resized and the publication is much smaller.

Q. I see.

A. So if you trace it, if more correctly to trace it, to trace is the objective,

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you would use to see like this in the microscope.

Q. And you could use the optical micrometer in order to measure to the extent necessary?

A. Yes, I can.

Q. Anything else about this image?

A. No.

Q. Let's go to page 26, image 3a.

A. Yes.

Q. What's the purpose of this image?

A. This image shows the nerve in H&E stain.

Q. What is the significance of showing the nerve; just the fact that you can show it? Is there any damage to it or any issues associated with it?

A. It's normal nerve, it's present within this mesh scar plate, it innervates the tissue which is inside and outside of the mesh. It can become trapped.

Q. Is it trapped in this image?

A. Well, it is in scar tissue. So it's trapped in scar tissue.

Q. Is there any indication that this nerve is damaged in this image?

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A. Not from this power, I don't see any -- "damage", you mean atrophic degenerated or damaged in terms of physical damage?

Q. Any kind of damage.

A. It is in scar tissue. For a nerve to be in scar tissue, is not a healthy environment.

Q. But not all nerves in scar tissue produce symptoms, correct?

A. Not all.

Q. And you can't tell by looking at this image, whether the nerve in Figure Set 3a is producing any symptoms, correct?

A. Again, it depends on timing. It may produce symptoms at one time and not produce at another time.

If this specific nerve was producing pain sensation, it would be difficult to determine.

Q. But you can't tell, looking at the nerve in Figure Set 3a, whether that nerve is producing symptoms for this patient, correct?

A. I can tell you that this nerve is in a situation when it can produce symptom. This is the main thing I can say, it can because it is in an abnormal environment.

Q. And the abnormal environment is

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the presence in the scar tissue?

A. Yes. In addition to be present inside the mesh.

Q. Okay. Well, it's adjacent to the mesh, correct?

A. I don't know. There might be fiber right there.

Q. Okay.

A. So it can be inside or outside, it doesn't matter. It's in scar tissue, it's abnormal environment, it can produce mesh. And we know that traumatic neuromas, which is the formation of a mesh in scar tissue, is a painful lesion. This is an established fact.

Q. But there's no traumatic neuroma in this image, correct?

A. A mesh is deformed, we can see it's getting there.

Q. Can you see a traumatic neuroma in this image, 3a on page 26?

A. The formation is not significant to call it a traumatic neuroma. So in this specific image, I would not use that term.

Q. Now, can you tell whether the nerve on page 26 that you show is a motor nerve?

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A. It's a mixed nerve.

Q. What do you mean by "mixed nerve"?

A. "Mixed" means they're both afferent and efferent, or motor and sensory signals going back and forth.

Q. How can you tell it does both? Do all nerves do both?

A. Peripheral nerves, yes.

Q. All of them?

A. Except for head.

Q. Okay. So are all nerves in the body, peripheral nerves, capable of mediating pain?

A. Except for cranial nerves.

Q. Okay. And what's the basis for your understanding in that regard?

A. It's a basic knowledge, it's in the textbooks.

Q. Okay.

A. There is some very small proportion of nerves, peripheral nerves, less than 5 percent, which are only sensory. So some of the nerves will be only sensory. But there are almost no, only motor nerves outside of the cranial nerves.

Q. Can you, by light microscopy,

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distinguish among the type of nerves which you see?

A. What do you mean, what type of nerves?

Q. Well, sensory and motor nerves?

A. We just agreed that they're all mixed.

Q. You said that, okay.

Is there any way for you to distinguish by light microscopy which nerves are capable of mediating pain?

A. They all are.

Q. Okay. 5 percent you said, where are they?

A. 5 percent is still sensory. So all of them can deliver pain. Some of them, 5 percent, may not be able to do any motor function, but they will still be able to transmit pain. And it also depends on the size, because once you go into the very small branches, they become more specialized. If you go into the large trunk, then you get all of them mixed together.

Q. When you talk about going into the nerve twigs, that's what you're talking about, right?

A. Fibers, individual fibers, yes.

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Q. Then they become more specialized; what do you mean by that?

A. So they may have more function for sensory or motor function.

Q. So as the nerves break into twigs, will there be some nerves that don't mediate pain, or they still mediate pain?

A. Fibers. If you go into fibers which is even smaller than twigs, which is individual axon, those will have individual function.

Q. And what are we looking at nerves here; are we looking at twigs, fibers, or are we looking at nerves?

A. It's a nerve. It's thicker than a twig.

Q. Okay. And what is remarkable about what you see in Figure 3a; anything more than you've just described, the presence of a nerve adjacent to mesh?

A. No, just everything else -- we discussed everything significant.

Q. Now, the polypropylene in the lower left-hand corner image, that's blue polypropylene, correct?

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A. That's correct.

Q. And it's folded over as a part of the sample preparation process or microtoming process, correct?

A. That's correct.

Q. This is a 4 micron thick slide, correct?

A. About 4 microns, plus or minus.

Q. I don't see bark on that polypropylene. Do you see any bark on the polypropylene?

A. There is a faint line here, I don't know if it's there or not.

Q. When you say "there," you're not pointing to the polypropylene. You're pointing to the circular area to the left of the polypropylene adjacent to the tissue, correct?

A. Yeah. Curving linear, yes.

Q. And you're suggesting that that may be some bark?

A. Yes.

Q. And why do you say that?

A. Because it looks like it.

Q. Okay. And this is magnified at 20 times?

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A. Yes. For this specific image, about 20 times -- 20 times objective magnification. The magnification itself is higher, because there's also an eyepiece, but eyepiece is fixed.

Q. Look at the right side of that image with the polypropylene. It's folded over, on the right side; you'd agree with me there is no bark?

A. Not visible bark.

Q. Okay. If we go to page 27, set 3b.

So 3a comes from the images from the consolidated cases, correct?

A. That is correct.

Q. So we should have this slide, I think. So paragraph 3b, so set 3b on page 27 says, "additional TVT cases".

Are you able to tell me from which case this slide comes?

A. I can only tell you that the top panel is from a newer case, and the bottom is likely from an older case.

Q. So they're two separate cases?

A. Yes.

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Q. Do you have any idea from looking at this, how long the mesh was implanted in these people?

A. No. Not at this magnification.

Q. And other than showing the presence of nerves within the mesh scar plate like you did on page 26, is there anything significant about your findings on page 27?

A. The only difference is that in top panel, you can clearly see that this nerve is within the pore.

Q. Are you suggesting that this nerve is inside of a single pour in the mesh?

A. Somewhere within the mesh.

Q. Okay. Not within the pore itself?

A. It can be within the pore.

Q. Do you know?

A. It also depends how you define the pore. Pore is a hole in the mesh structure, yes, it is within the space in the mesh structure.

Q. This is 20 times magnification, how far is it from one yellow to the other yellow?

A. At 1.5 millimeter. Between 1 and 1.5 millimeter.

Q. Is there anything abnormal about

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the nerve that's depicted on page 27 in the top frame?

A. It's in the scar and it's in the mesh, that is abnormal.

Q. Other than being in the scar plate, is there anything you can tell by light microscopy about abnormality in that nerve?

A. Otherwise, the nerve looks healthy, it would conduct pretty healthy pain signals.

Q. Okay. Same thing for the lower frame. Other than the presence of the nerve within the scar tissue, is there anything that you can tell from light microscopy about the general health of the nerve?

A. Same thing, it's not degenerated, therefore, it can conduct pain signal.

Q. As you look at the image on the lower left on 3b, the white in that image, again, is where polypropylene was?

A. Yes.

Q. And as you come down around from about 6 o'clock to about 9 o'clock, there's no bark there, is there?

A. No. I don't think so.

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Q. Let's go to page 28. Page 28 is additional TVT cases.

Is this one mesh or two? One patient or two, I guess I should say.

A. This is hard to say, both are come from earlier cases. I probably have thousands of images by now, so it will be hard.

Q. But you can't tell me from which patient they come, or which case they're from?

A. I may or may not be able. It would be checking if it's in a specific folder or just in pooled images.

Q. And your description again, below is, "Innervation within the mesh scar plate, H&E, 20 times magnification."

Other than showing the presence of these nerves in the mesh scar plate, is there anything that indicates to you by light microscopy that these nerves are unhealthy?

A. Well, it's the location. You see, it's slightly curved, it's inside the pore.

Q. Which one are you talking about now, please?

A. The upper panel.

Q. Okay, thank you.

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A. There are two nerves, one is here, one is there (indicating).

Q. And you indicate that with your two arrows --

A. This one is gone.

Q. Okay.

A. So it is a location -- it's not the nerve itself, it's the location is abnormal.

Q. Is there anything that you can tell me by looking at this image by light microscopy that these nerves were producing symptoms in the patient?

A. The question is, if they can.

Q. Can you tell me by looking at this image in set 3c, that these nerves are causing symptoms in the patient?

MR. ORENT: Objection.

THE WITNESS: Again, as a pathologist, I can only estimate the probability. If it can, if it's in abnormal location, if it's causing a lot -- first of all, it's out of the body now, so it cannot cause anything. But when it was in the patient, it could.

BY MR. THOMAS:

Q. Could?

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A. Could produce symptoms all the time, or one specific time, or only once in a specific moment, it's hard to say.

Q. And it could be a nerve positioned as it is, that never produced any symptoms, true?

MR. ORENT: Objection.

THE WITNESS: Some of them probably not producing anything.

BY MR. THOMAS:

Q. Okay. And the same thing about the image below on Figure Set 3c on page 28, other than presence of the nerves in the mesh scar plate, anything remarkable about this image?

A. No. Nothing beyond what we've discussed.

Q. Let's go to page 29.

A. Yes.

Q. What are we showing on page 29?

A. The same features of innervation of the mesh scar plate. But now in S100 stain.

Q. Now, is there anything other than presence of these nerves in the mesh scar plate that indicates to you that these nerves were causing pain in the patient?

A. They are in abnormal location.

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Q. And we've already agreed that nerves, even in an abnormal location, may not be producing pain, correct?

A. Yes, but more likely they will produce pain.

Q. Are you saying that every nerve within the mesh scar plate more likely than not is going to cause pain?

A. Through one mechanism or the other, there will be zero mechanism at one point that can produce pain, it may not be chronic pain continuous, but I mean, in a specific movement you have start forming the mesh, so it can cause pain.

Q. Let's talk about this for a minute. Doctor, if you look at page 29, and 28, and 27 and 26 --

A. Yes?

Q. -- it's fair to understand that for every mesh implantation, there are going to be nerves that are going to be in scar tissue.

A. Are you talking for all meshes? Regardless of location, or just --

Q. I'm talking about slings. Stress urinary incontinence slings, TVT, Prolene.

A. So for slings, there will be

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innervation, at least those samples I examined, there will be innervation in all of them.

Q. Okay. And complaints of pain for slings, TVT slings, you'll agree is less than 5 percent?

MR. ORENT: Objection.

THE WITNESS: For the specimens I received?

BY MR. THOMAS:

Q. I'm talking about the studies on the topic?

MR. ORENT: Objection. Outside the scope.

THE WITNESS: Now we're talking about what I received and what is still in the patients. Because studies were clinically done based on clinical -- clinical symptoms for the samples or slings which are still in the body.

BY MR. THOMAS:

Q. Very simple question.

How do you explain findings in the clinical studies that pain is a complaint of patients in less than 5 percent of the time, when you say in every mesh that you see, that there are nerves within the scar plate?

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A. Well, first of all, let's start with 5 percent.

That number would have to be specific for our study. There is a range of reported pain anywhere from 5 to 40 plus percent. It depend on methodology, if the patients were followed in time correctly, if there was correctly of follow up time. So the 5 percent is a questionable number.

Q. Can I interrupt you there, if you don't mind. Let's take your upper bound of 40 percent?

A. Yes.

Q. So you have, by your own statement, even in the worse case scenario, you have 60 percent of the sling patients who don't experience pain, correct?

A. Who do not complain to the point when it's recorded.

There are multiple reasons why it may not be recorded, they may still experience some pain. Maybe it's not serious enough to be recorded, maybe it's not serious enough -- there will be some patients which have no pain at all. There will be some patients which have so little pain, only in a specific moment, that it's not

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worth reporting. Some of them don't report it and so forth.

And then there will be patients that there is so severe pain, the mesh needs to come out. There will be a range of sensations and personal perception.

So, from my perspective, when I examine specimens, I report what is abnormal. To what degree it's causing clinical symptoms, it depends on many factors. If you want to -- you cannot look at the human body as a machine. I mean, there is part missing, it's not going to work. Or if there is wire loose, I mean, it may cause some problems.

So, there will be a range of -- or degree of pain sensation and a range of personal attitude so this will effect the recording of clinical symptoms.

On the histology side, again, there will be a range of how many nerves are involved, one or two, or a really high density. To what degree they are involved, some of them will have such a strong deformation, that there is 100 percent probability that it will cause pain.

Q. Let me ask this question --

A. So that's the complexity of the

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situation. I mean you cannot separate it sharply, okay, 5 percent for this, 5 percent for that. It can cause a pain. This is abnormal location, this is abnormal situation, this is a pathological finding.

Q. Let's talk about this for a minute. So the pages we've just been through, we've talked about, on pages 26, 27, 28 and 29, and it goes on to 30 and 31, and on to 33. But just for those for now.

Is it fair to understand that in every mesh that you've analyzed - regardless of manufacturer - in the pelvic floor, for treatment of stress urinary incontinence, you find nerves in scar tissue?

A. Yes.

Q. Okay.

A. The degree of innervation will be different, there will be a degree of also nerve deformation within the mesh, but strictly saying there will be innervation of the scar plate in almost all patients.

Q. Have you made any attempt to differentiate across manufacturers, the extent to which the innervation of the scar plate varies?

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A. No.

Q. Have you made any attempt to differentiate across types of mesh products, the extent to which nerve innervation varies?

A. I may in the future, I haven't done it yet. But I may in the future.

Q. Okay. So is it fair for me to understand, and the record to reflect, that for every mesh implanted for the treatment of stress urinary incontinence, it's your opinion that there will be nerve innervation within scar plate, that you think is capable of causing pain?

MR. ORENT: Objection. I think his testimony is every mesh that he's looked at. Manufactured, that he's looked at.

I don't think Dr. Iakovlev has any opinions about mesh he's never looked at, brands he's never looked.

THE WITNESS: Yeah, that's correct.

BY MR. THOMAS:

Q. Okay. Let me ask you this question --

A. Let's repeat the question, then I can answer it in more...

MR. THOMAS: Would you read it back, please?

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-- REPORTER'S NOTE: Question read as recorded above.

THE WITNESS: Oh, as I said, I can only testify or make opinions of what came out of the specimen. And I told you earlier, that there is -- I have been dealing with those specimens which caused complications already.

BY MR. THOMAS:

Q. For every mesh sample that you've looked at for mesh use for the treatment of stress urinary incontinence, have you found mesh innervation in the scar tissue?

A. Almost all, yes.

Q. Any you haven't?

A. If it was a small sample, maybe one or two, I couldn't find nerves.

Q. Is that because -- do you have an opinion, is that because the sample was too small, because it didn't exist, or do you have an opinion?

A. I cannot say beyond that, I just didn't find it. It could be sampling issue, it could be not. Again, I cannot state what I don't know.

Q. And how many have you seen?

A. Individual cases.

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Q. How many have you seen?

A. Less than five.

Q. How many total cases have you seen?

A. Oh, from slings?

Q. Yes.

A. About 100.

Q. About 100. And less than five you have not seen nerve innervation within scar tissue?

A. Yes.

Q. And you don't know whether that's because it is a sampling error or because there wasn't any nerves in the scar plate?

A. That's correct.

Q. Is it fair to say, based on your experience as a pathologist, that you would expect that when mesh is placed for the treatment of stress urinary incontinence, that nerves would be encapsulated by the scar tissue in the healing process?

A. They can. If they become trapped in the scar tissue, each single implanted mesh, we would have to do autopsy series. I cannot go beyond what I see in explanted meshes, and all explanted meshes came out for complications. And

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almost all of them, or a large proportion had pain as a symptom.

Q. Again, the cases you've received have been complications?

A. Yes.

Q. And of course you know that people have mesh removed for reasons other than pain, don't you?

A. In hernia surgery, yes.

Q. Do you know whether or not patients have mesh removed for reasons other than pain?

MR. ORENT: Objection.

THE WITNESS: There might be an overwhelming other complaint, like erosion or infection, but in almost -- I don't want to stick a number, but most of these patients complain of some degree of pain.

BY MR. THOMAS:

Q. Have you have investigated, as a part of your work in this case, the reasons why patients have mesh removed?

A. There's always a reason.

Q. I understand that. Do you know what they are, and percentage wise, how they

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breakout across a patient population?

A. You mean the driving reasons for implantation?

Q. Yes.

A. It's in the paper. At least in those 164 samples.

Q. And that's the paper you did with Dr. Blaivas?

A. No. The degradation paper.

Q. Okay.

A. But there's always a driving reason for explantation. There may be driving reason for explantation is erosion, but then pain is attributed to erosion. So it's not indicated as a main reason of explantation.

Q. You can have voiding dysfunction?

A. Okay. In a voiding dysfunction, but again, voiding dysfunction usually what happens, you have a strong compression against urethra, and this produces pain due to compression. So there will be a mixture of mechanisms for pain.

Q. Are you suggesting that voiding dysfunction is subsumed within the pain that's reported in these studies?

MR. ORENT: Objection.

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THE WITNESS: No, it's combined. It can be combined, this pain.

BY MR. THOMAS:

Q. Okay.

A. To cause void and dysfunction, even to compress urethra to a degree that the outflow is obstructed.

Q. Are you aware of any studies which have analyzed meshes removed because of pain, compared to meshes removed for other reasons in comparing the histology of those meshes?

A. We're doing some work in hernia specimens.

Q. But in terms of published peer-reviewed studies today, are you aware of any studies out there, which compare the histology of meshes removed for pain, and meshes removed for non-pain reasons?

A. That's a very good question. Why, after 50 years and a large proportion of specimens removed for pain, there is no histology study. Why has this not been done?

Q. So did you do a literature search of that?

A. Of course I did.

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Q. And you didn't find any studies that compared the histology of mesh removed from patients who complained of pain, compared to the histology of patients who had mesh removed for non-pain reasons?

A. There were descriptions in hernia publications. I mean in meshes removed for hernia repair.

Q. Which studies, do you remember?

A. 2005, Klosterhalfen. He put the picture of deformed nerve, and he states that in his experience, over 60 percent of the meshes removed for pain have some degree of nerve involvement.

Q. Do you view Dr. Klosterhalfen as authoritative in this area?

A. Yes. He's an authority, he's one of the oldest researchers.

Q. Do you know whether Dr. Klosterhalfen has ever investigated the precise question about whether the histology of mesh removed for indications of pain is different from the histology of mesh for -- from patients removed for non-pain reasons?

A. That's what he stated. Over

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60 percent of the specimens removed for pain showed nerve involvement.

MR. ORENT: Before we go on to the next question, you had cut Dr. Iakovlev off from answering. He started to say "but there are other authors", if you want to just continue.

THE WITNESS: Yes. There are other descriptors of meshes removed for pain, and they would find nerve involvement with traumatic neuroma. Those are, I think individual cases, not the series.

Again, same histology. They were trying to figure out what was wrong, what was causing pain, and they found nerve involvement. And that was done before I started researching my nerves.

BY MR. THOMAS:

Q. Would you expect more or less inflammation to be seen in histology of meshes removed for pain than meshes removed for non-pain reasons?

A. To a degree. My research in hernia showed that foreign body inflammation is a component of pain mechanism. So those meshes which were removed for pain only, they continue to have

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relatively steady, pronounced foreign body reaction many years after implantation.

And those which were removed for recurrence, they show a trend down. So at the beginning, there is inflammation, then it goes down.

So by the time of explantation, if it happens eight years or ten years after explantation, foreign bodies subsided; which is different from those which were removed for pain.

Q. So are you able, from your research, in your work, to form an opinion as to whether mesh removed for purposes of pain, the histology will show higher rates of inflammation than the histology for meshes removed for non-pain reasons?

A. So before we go into the individual findings, you're trying to split it into what is causing the pain, nerve entrapment and inflammation or something else.

This is a complex process. There are multiple factors which are playing, together with patient perception of pain and reporting of pain.

So with this type of complexity, we cannot separate one individual feature. Overall,

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there's a pool, if we collect enough, we can see the difference. For each individual patient, how much of this feature, or that feature is playing a role in each individual symptom, will be very different from patient to patient.

So overall, the higher degree of foreign body reaction is associated with higher rates for chronic pain.

Q. And that's based on your research or other published research?

A. Foreign body has been worked up quite a bit in published histological studies. How much of that was specifically determined, comparing two groups or three groups, it's difficult to say, I don't remember right now.

So it is a combination of what was published before, and what I find in my samples, so that's -- that would be a basis for my opinion.

Q. Is it your opinion that results in the hernia literature on the issue of association between inflammation and pain, are transferrable to the pelvic floor?

A. Some are, yes. Not everything, but some are.

Q. Okay. And why would it not be?

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A. There are different anatomical locations, different physical factors acting on the scar plate. It also crosses many anatomical planes in the pelvis. While in the abdominal wall, and it's parallel to anatomical planes.

Q. I'm trying to get through this for a second. If you'll look at pages 30, 31, 32 and 33. Are the images on those pages additional depictions of nerves within the mesh scar plate?

A. That's correct.

Q. Is there anything else significant about those images other than they show innervation within the mesh scar plate?

A. No.

Q. On page 33, Figure Set 3h, in the upper right-hand corner, you've called out what you've described as a "neurovascular bundle"; what is that?

A. Most of the larger nerves in the medium size arteries, become together. One artery, two veins, and one nerve, that's how it works. And the nerve just starts bleeding, so the nerve goes its way and artery goes its own way.

So in this specific case, an artery and a nerve are still together.

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Q. Okay. The brown is the nerve, correct?
A. Yes. I mean, there are some other brown, probably picking up some other stuff, but this is --
Q. Where is the artery?
A. In the blue. You can see streaming, it's not a really high resolution.
Q. What is the significance of the neurovascular bundle as depicted in that image?
A. Well, see, it is in the tight spot. So this is really as compartmentalized as it gets, and slightly deformed.
So if you move this mesh around, the fibers will start compressing on the neurovascular bundle. It may cause obliteration of the artery, or can impinge the nerve.
Q. Is there any impingement shown in this image?
A. Well, it's deformed.
Q. Is there any impingement shown?
A. It does, because it's deformed, it's curved.
Q. And you're referring now to the lower right-hand image?

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A. That's correct.
Q. Is there anything you can tell by looking at that image, whether that curved nerve was causing pain in this patient?
A. I can say the probability of this causing pain is much higher than a nerve which is not deformed. Like something like this on page 31.
Q. You can't rule out by looking at the image on page 33, where you show the curved nerve, you can't rule out that that nerve is not causing pain, correct?
A. I think we're going back to the same issue. You're taking human body as a machine, it's not. Medicine doesn't happen like that. So there are many, many, many factors which cause.
If the same image we put in MRI image, and this deformation would be on the root coming from the back, the radiologist would report that there's impingement of a root. And that's how back pain occurs that's radiating to the leg, and so forth. So this is a much smaller scale, the same mechanism.
Q. Do you know whether this patient was complaining of pain?
A. Most likely she was.

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Q. Do you know?
MR. ORENT: Objection.
THE WITNESS: With 100 percent certainty, no.
BY MR. THOMAS:
Q. Okay. And you talked about an obliteration of the artery. Does the image on page 33 in the upper right show an obliteration of the artery?
A. No, not this image.
Q. Other than the nerve impingement that you've described, and the potential for obliteration of the artery, is there anything unusual about the depiction of the nerves in those images?
A. No.
Q. And I need you to go back, because I didn't ask you that question about the prior two pages, 30 through 32.
Other than the depiction of the nerves within the scar plate, is there anything about the nerves that are seen there that cause you any concern about the potential of those nerves to cause injury?
MR. ORENT: Objection.

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THE WITNESS: So going back to mechanisms of pain. So there are two mechanisms, or two major groups of mechanisms to cause pain. First, you affect the nerve itself. So you impinge it, squeeze it, becomes deformed and that can be felt as pain, the nerve itself, the nerve trunk.
The second group of mechanisms is when you affect the receptors. And the receptors can be affected, it can be again a mechanical trauma, cutting, compressing, burning, chemical trauma, ischemia, then the receptors are signalling pain through the nerve. So for smaller branches, the significance is that the receptors now can pick up the signal of nerves -- of pain, and then it will be delivered through these branches, so it just shows that this tissue can sense pain.
BY MR. THOMAS:
Q. Okay. This tissue is capable of sensing pain?
A. Yes.
Q. Not that it is in fact sensing pain in the body at the time?
A. If you have other mechanisms to deliver pain, it will be -- it will be causing pain.

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Q. Correct.
A. Now, if you go to page 33, this will be an example where it would be directly effecting the nerve trunk. Impingement of the nerve.
Q. Now, are you able, in these images, 30 to 33, to show me any nerve receptors?
A. You mean receptors, nerve endings. When it goes really small, you can see really fiber, and it is -- most of the ends will have no staining, because they just disappear. But I mean, you'd have to go in higher magnification.
Q. So with the magnification you have here, you're not able to identify any nerve receptors; is that fair?
A. No, not in these pictures. It's too small magnification.
Q. I have to ask the question again because you answered "no" to a negative question. It's fair to understand that based on the magnification that you have in these images on pages 30 to 33, you can't identify any nerve receptors, correct?
A. I cannot see nerve receptors at this degree of magnification.

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Q. Thank you.
If you go to page 34, what is the significance of this image?
A. This shows another severely deformed nerve. So this would be a mechanism for pain through impingement.
Q. And the severely deformed nerve as you described it, is the brown portion, stained brown?
A. The dark brown portion or dark brown structure.
Q. And in the lower left-hand corner, the white area is where the polypropylene is or was, correct?
A. That's correct.
Q. And what's the significance of the dark blue and the border of that area? Is that the staining mechanism, or does that tell you anything?
A. Can you point it? So significance of what?
Q. The darker blue.
A. This dark blue?
Q. Yes.
A. That's inflammation.
Q. Okay. And the upper is 2.5 power, and the lower one was four times; is that correct?

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A. It's a typo, it should be 40.
Q. 40?
A. 40. Somewhere between 40 X and 50 X. Again, the cropping factor there, the magnification there is not exactly...
Q. And these are, again, additional TVT cases, and you have not supplied us the slides for these cases, correct?
MR. ORENT: Objection.
BY MR. THOMAS:
Q. In this case?
A. That's correct. These are previous TVT cases.
Q. On page 35 --
A. Yes.
Q. -- you suggest degeneration of affected nerves; tell me what you mean by that?
A. So you see the inner portion of the nerve lost myelination. So there is degeneration of myelin sheath in the nerves. It means that these nerves cannot deliver, or most likely not deliver irregular signals.
So earlier you were asking about the abnormality, this is the abnormality that we're talking about, this is the nerve degeneration. In this case, if this part is sensory, inside, it means that the area is numb.
This part of the nerve cannot sense pain or innervation of that part of the body, which goes through this nerve, may not experience any pain; it's numb.
Q. And that's the portion you're referring to in the lower right-hand image with the arrow, correct?
A. That's correct. So the abnormality of the neural section indicates the other process, of loss of sensation, loss of pain sensation.
Q. Do you know what a Renaut body is?
A. Say that again.
Q. Do you know what a Renaut body is? R-E-N-A-U-T.
A. I think I've seen this term, but I don't remember it.
Q. Okay. Does the S100 stain all components of the nerve?
A. It only stains schwann cells.
Q. When you reached the opinion on page 35 that that shows a degeneration of the

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nerve, did you rule out the presence of nerve structures other than schwann cells that might be present?

A. There might be axons still there, but that's not the point. The point is the nerve is degenerating.

Q. And what's the clinical impact of the degenerated nerve?

A. I just told you. There are fibers, which are in the area, mainly not function. It means that if they are sensory fibers, they may not deliver signals. So that area which is innervated through those fibers, will be numb. You will not feel anything in that area.

Q. So it will not cause pain?

A. In the reverse, it will not feel anything.

Q. But if it doesn't feel anything, does that mean that it does not cause pain?

A. Including pain. It will not feel touch, it will not feel temperature, it will not feel pain.

Q. Okay. Anything else remarkable about it then?

A. No.

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Q. If you go to page 36, Figure Set 4.

A. Yes.

Q. You have, "A neural ganglia in additional TVT cases."

Again, these are cases that you previously worked up?

A. That is correct.

Q. What is a neural ganglia?

A. Neural ganglion is like a switch box, or connection box for the autonomous neuro system. The neuro system which is innervating in the organs rather than skin and mucosa.

Q. What is the significance of the presence of this image of the neural ganglion?

A. It tells you that some of the nerves, which we see in the specimens are autonomous. So some of them go into the bladder. That's one -- well, one important aspect of this.

The second important aspect is that the ganglia themselves can be affected by the image.

So in first case, the nerves can be affected, which are further away from the ganglia. And second case scenario, the ganglia themselves.

Q. Is there anything about this image

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on page 36 -- strike that.

This is one image, the second one you've labeled, so it's just one image?

A. That is correct.

Q. Is there anything about the image on page 36, that you can tell by light microscopy, that there's anything abnormal about the ganglia that's depicted there?

A. To begin with, as we saw the nerves, the location was abnormal. So it's in the scar tissue and it's inside the mesh.

Q. Is that the only thing about this image and the ganglia that causes you concern?

A. No.

Q. What else?

A. I mean, that's about it. I don't have any other concerns.

Q. Thank you. Page 37 you have: "Innervation of mucosa overlying the mesh, H&E and S100 of the same tissue area, four times. Additional TVT cases."

Again, these are cases outside of the consolidated group, correct?

A. That is correct.

Q. And are all these images just four

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times?

A. The degree of magnification on the top image is slightly lower, and magnification on the lower is slightly higher. Again, this is not -- it's hard to say exactly what's the degree of magnification. Because they've been taken through a camera and sort of objective, and then cropped, and then resized to be reprinted so...

Q. What is the significance of the image on the top where you showed mucosa, distorted mucosa, and a measurement of 1 millimeter?

A. Significance is that the mesh is right under the mucosa. So, if you touch the mucosa, even if it's light pressure, it immediately gets compressed into the mesh. It can be exposed, I mean, the mucosa can breakdown.

Q. This is from the Edwards case, isn't it?

A. It could be, I don't know. It's old picture, it could be from the Edwards case.

Q. And this does not show an exposure, correct?

A. It's not exposed, yes.

Q. It's not an erosion either yet?

A. In this specific image, it's not

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exposed.
Q. Okay. And what's the significance of the distorted mucosa?
A. Probably, it was getting close to the exposure site. I don't remember specifics.
Q. Okay. But is it simply the fact of the location of this mesh related to the mucosa that you're pointing out here?
A. That is correct.
Q. Is that a surgical placement issue?
A. Not exactly. It can migrate, it can move centimeters within the body.
Q. Or a surgeon can place it there, correct?
A. Both.
Q. Yes. And you're not able to tell from this image, whether the surgeon placed it there or it moved there from somewhere else, correct?
A. No. I know that all of them are covered by mucosa after surgery. That's what surgeons are trying to do.
Q. So again, I asked a bad question. You can't tell from looking at the image, whether the surgeon placed it there, or

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whether it migrated there, correct?
A. That's correct.
Q. Thank you. And what's the significance of the two images below that on Figure Set 5?
A. It's the same image, the right copy is labeled, the left one is not labeled. It shows that the tissue in between mucosa and the mesh is innervated.
Q. I see.
A. So if you compress mucosa, you are hitting the receptors, hence small nerve branches at the same time.
Q. Anything abnormal about the nerve branches and twigs that you depict in those images?
A. Just the location.
Q. Okay. Page 38, "Additional TVT cases." What does this show?
A. The same as it says on the previous page, superficial location of the mesh, overlying mucosa, innervation of the tissue and the mucosa.
Q. And other than the presence of the nerves in the mucosa, and the position of those nerves relative to the mesh in the mucosa, is there

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anything else remarkable about that image?
A. No.
Q. If we go to page 39, what is vascular dilatation?
A. When the vessels are being distended, so the outflow from the vessels is obstructed for varying reasons. So there is more fluid coming in, than fluid coming out.
Q. And what does mesh have to do with vascular dilatation?
A. It caused it.
Q. How do you know that?
A. Because normally vessels are not distended like this, there is a reason why the outflow is obstructed.
Q. Are there any other causes for vascular dilatation?
A. In normal tissue?
Q. Yes.
A. There are some other, like typical example is hemorrhoids.
Q. I'm sorry?
A. Hemorrhoids.
Q. Hemorrhoids?
A. Hemorrhoids.

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Q. I'm sorry. That's a southern West Virginia way of saying it, I apologize.
A. Okay. So there is dilatation of the vascular structure, blood stays in. If it's lymphatic vessel, lymph will stay, so it will distend and it becomes larger.
Q. Now, what is statis, S-T-A-T-I-S?
A. Stasis, sorry.
Q. Stasis. So stasis and tissue edema; what does that mean?
A. Stasis means that the fluid is stagnant in the vessels. So it accumulates there, it doesn't outflow. And then after some time, this fluid starts seeping into the tissue. So because the blood vessels, or lymphatics are so backed up, fluid starts going into the tissue; that's how edema happens.
Q. Okay. The blue in the image is polypropylene?
A. Yes.
Q. And that is moved in the image by sample preparation?
A. That's correct.
Q. The artifacts?
A. Yes.

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Q. And do you see any bark around the polypropylene in those images?
A. Here.
Q. You pointed to the white. I'm looking at the blue polypropylene itself. There's no bark attached to any of the polypropylene, is there?
A. Probably there is, but so low magnification. I can see it clearly in this space.
Q. And you're referring now to the upper right-hand corner and the black mark at the lower right, correct?
A. Just above it -- no, no, here.
Q. Are you talking about --
A. The faint line. This faint line. (Indicating).
Q. Oh, I see, okay.
And what's the clinical significance of the vascular dilatation and statis tissue edema?
A. There's pressure inside. If fluid accumulates to a degree, and then it starts pressing in tissue, there will be pressure accumulating.
Q. And to what extent can you determine whether this pressure is present in an

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area larger than what is presented in this one slide?
A. What do you mean?
Q. Well, this obviously depicts these findings within this slide. This slide is 4 microns thick, and I don't know how far across.
A. About two and a half, three millimeters.
Q. Okay. Can you tell whether this finding is present anywhere else in the woman from which this was explanted?
A. Oh, it's patches. Somewhere it's dilated, some areas are edematous, some are not. Sometime the entire mesh is just sewed, or is shown edema or dilatation. It depends, variables.
Q. And so you're unable to say, looking at this figure on page 39, Figure Set 6a, whether what you've described here was causing symptoms in this woman, correct?
MR. ORENT: Objection.
THE WITNESS: Oh, I think we talked about this before. Causing symptoms is a complex process, and perceptions.
So this is abnormal mechanism, it is a factor in pain mechanisms in some other areas.

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Take hemorrhoids, you ask some patients, have them painful; some patients have them not painful.
BY MR. THOMAS:
Q. I understand that. But it's also fair to understand that this woman may have had this issue in the histology, as you've described it, but not be experiencing any symptoms because of it, correct?
A. That's correct. The main thing is it's an abnormal finding and it can cause pain.
Q. Okay. Do you know whether the images that are on page 40 are --
A. Stasis.
Q. It's the same patient, 6a, 6b?
A. Could be, I'm not sure.
Q. You don't know, okay.
Again, the blue is polypropylene?
A. Yes.
Q. Are you able to tell in 6b, the long, narrow white space in the lower left hand, whether that is polypropylene that's present or not present?
A. I'm not sure. The largest part is difficult. I can see a little bit of the degradation bark can be sitting on the non-degraded

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bark and -- oh, I can see some of the mesh fibers left here in this space.
Q. Okay. I'm looking at the area above that one, though. This one (indicating).
A. Yes, it's folded and it trapped some of the dye.
Q. Now how do you know that's folded as opposed to just mesh, part of the interstitialcy or part of the mesh being right adjacent to it?
A. Do you see this line, or this slice, or cross-section of the fiber, it's folded like this, and then there's a little bit of a dye in this space, you can see it.
Q. So what you're showing here is vascular dilatation stasis again?
A. Yes.
Q. Tissue edema?
A. Yes.
Q. Anything else remarkable about this slide?
A. No.
Q. And the top is four times magnification, and the bottom is ten times magnification?
A. That's the best approximation.

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Q. And my expert should have this slide, correct?
A. Yes.
Q. Since you did 6a, 6b, 6c, does that mean that it's from the same patient?
A. No. They group by the feature.
Q. Okay. So you don't look at it?
(Reporter sought clarification.)
A. Feature. So if it's the same feature, it's the same figure number, but if it's different images on different pages, they are labeled A, B, C, D.
Q. What is the significance of the edematous scar; the edema, loose scar?
A. It's edema, the same thing we discussed before. The fluid stays in it, it builds up pressure and can compress the structures.
Q. The same on page 41, 6c?
A. That's correct.
Q. Anything remarkable about the image on page 41 beyond what you've described?
A. No.
MR. ORENT: Counsel, I'm wondering if it's a good time to take a quick lunch break?
THE WITNESS: It feels like it.

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MR. THOMAS: Sure, absolutely.
-- OFF THE RECORD DISCUSSION --
-- RECESS AT 1:01 --
-- UPON RESUMING AT 2:11 --
BY MR. THOMAS:
Q. Let's go to page 42 of your report, please. I see you're open to it already.
A. Um-hum.
Q. Figure 7a says, "Involvement of striated muscle by the mesh, H&E, 4 times. Additional TVT cases."
Again, this is a case that is not contained within the consolidated cases?
A. That is correct.
Q. Can you tell whether this is TVT or TVT-O?
A. No.
Q. Does the fact that it's involved striated muscle help you at all?
A. To a degree.
Q. Why would that influence which kind of mesh it is?
A. It helps, because most frequently if I see striated muscle, it's transobturator tape, but occasionally I see striated muscle in

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retropubic tapes as well.
Q. And what are you showing in Figure 7a?
A. I'm showing involvement of striated muscle in the mesh.
Q. Tell me what you mean by that.
A. Striated muscle can be incorporated right in the mesh, most likely mesh migrated into the striated muscle. Or sometimes it's just attached to it, so the fibrous capsule.
Q. On the left side is the actual slide, and on the right side you've filled in with a red, orange and a yellow, correct?
A. Yellow and red.
Q. Okay. The yellow is the polypropylene?
A. That is correct.
Q. And the red is what?
A. Red is striated muscle.
Q. All right. And you said "involvement of striated muscle by the mesh."
This shows striated muscle adjacent to, but not incorporated in the mesh, correct?
A. Some parts of this incorporated, sometimes it's just been fused, surface scar tissue.

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Q. Help me. Show me where it's incorporated in it.
A. Well, in this case --
Q. You're referring to the lower right?
A. In the lower panel, striated muscle is encircling one of the mesh fibers.
Q. Okay. What's the distance, in four times magnification from the muscle and the mesh?
A. Within 1 to 2 hundred microns, probably 100.
Q. Okay. And what's the significance of that finding to your opinions in this case?
A. Well, if the mesh is fused with the striated muscle, any contraction of the muscle will tug on the mesh and prevent muscle from free contraction.
Q. And what symptoms does that create?
A. The mesh is tugged, and you can feel the mesh moving, pulling the nerves and other tissues. So it's related to discomfort, feeling of pressure and pain.
Q. Once again, is it true that you can't say by looking at the images in 7a, that this

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patient was experiencing pain or discomfort due to the presence of the striated muscle next to the polypropylene mesh?

A. I cannot say the degree of sensation, but in this specific location, any contraction of the muscle will tug on the mesh. So there will be a degree of sensation, to what degree I cannot say.

Q. All right. Anything else remarkable about the images on 42?

A. No. Just striated muscle involvement by the mesh.

Q. So let's go to Figure 7b on page 43. You're using a different stain here, the desmin stain.

A. That is correct.

Q. What is the significance of Figure Set 7b on page 43 of your report?

A. Clearly, more visible in the picture.

Q. What is more visible?

A. Striated muscle.

Q. And that's yellow in this image?

A. No, brown. Brown is striated muscle.

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Q. Brown, I'm sorry.

A. Because for a non-pathologist, it would be hard to see where striated muscle is in H&E section, but when we use desmin stain, it demonstrates even the presence of striated muscle.

Q. I see. Are you able to tell me whether the image in 7b is from the same patient as the image in 7a?

A. No, likely not.

Q. Why do you say that?

A. Just my recollection.

Q. Are you able to tell me from what patient 7b comes from?

A. I may or may not.

Q. How about 7a, do you know who that came from?

A. Same thing, I may or may not.

Q. Okay. Tell me, please, the significance of the image in 7b.

A. Now, we can see clearly that muscle is on both sides of the mesh. So the mesh is sandwiched between striated muscle, surrounded by it.

Q. The same answers for 7b as 7a, that when the striated muscles touch the mesh there would be a tugging, discomfort and possible pain?

A. That is correct.

Q. But you don't know the extent to which those may manifest themselves from this figure?

A. The degree of sensation is difficult to predict, it depends on multiple factors.

I mean, it's clear that in this location striated muscle contraction will be restricted, and will cause movement of the mesh. But the degree of sensation cannot be determined.

Q. What about page 44? Sorry, let's go back to 43.

Did that cover the remarkable findings in Figure 7b?

A. No, I mean --

Q. Is there anything else remarkable about this?

A. We've covered everything.

Q. Thank you. Figure 8a, on page 44.

A. Yes.

Q. "Involvement of smooth muscle by the mesh, H&E, 10 times. Consolidated cases."

Are you able to tell me whether this is a TVT or TVT-O?

A. No.

Q. Okay. And you can't tell me which patient it's from as you sit here?

A. I can determine for this specific figures which patient it came from, because this image has been numbered by this time.

Q. And can you tell right now, or do you have to consult something?

A. No, no. I would have to go back and check the names of the files.

Q. I see, okay.

And what's the purpose of depicting the smooth muscle in this image?

A. To show that smooth muscle can also be involved by the mesh.

Q. Is the smooth muscle impacted in the same way as the striated muscle that you described in the last two slides?

A. In a similar way, yes.

Q. Okay. Is the point here to show that the smooth muscle is in close proximity to the polypropylene mesh?

A. That's correct.

Q. And similar to 7a and 7b, any

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contact with polypropylene with the smooth muscle may cause some discomfort, tugging or possible pain?

A. There is a little bit more to smooth muscle. Because smooth muscle is present in both vaginal wall and urethra and bladder.

So urethra and bladder have thicker bundles of smooth muscle. Vaginal wall has wisps of smooth muscle.

If mesh is in the vaginal wall, smooth muscle, which is in the vaginal wall, can be either attached to the scar plate. Or, if the mesh migrates, it incorporates smooth muscle inside the pores.

So if the smooth muscle of the vaginal wall contracts, the mesh will interfere. So this will be more of a sensation in the vagina, more likely during intercourse, whether the vaginal wall contracts.

Now, if we compare it with the smooth muscle of the bladder and the urethra, it's a different organ. So if mesh is interfering with those bundles, they may not contract correctly. So there may be interference with the function of urethra and voiding, urination. And also,

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sensation in the area.

Also, you should obstruct urethra through compression of it. The mesh is pressing against these thick bundles, and then compresses the urethra. So it's indication that position of the mesh was such that it was causing urinary symptoms.

Q. Are you able to tell from Figure 8a, whether this tissue sample is from the vagina or in the area underneath the urethra?

A. For Figure 8a, it would be difficult because it's an H&E slide. If I stain it with smooth muscle, then I can see exactly borders and position of the muscle. Or, I can see it in the microscope.

It's likely to be urethra, because the area is more compact and there are bundles of it, but I would have to look at the slide. But comparing between these two applications, I would favor the urethral muscle in this specific image.

Q. And it's fair to say that the muscle here has not yet been incorporated into the mesh, correct?

A. Not fully, but you can see that the mesh is --

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Q. Adjacent to?

A. Moving, or pressing against this bundle. It's partially compressed; you see the indentation made with the mesh here.

Q. Okay. And again, you don't know the extent to which the situation, circumstances described in this slide, may cause or contribute to discomfort, tugging or pain?

A. If it's urethral muscle, it can cause urinary outflow obstruction, because it's clearly pressing on this part of the muscle. So it's pressing on the whole urethra.

Q. But you don't know the extent to which it was removed for obstruction, or why the mesh was removed; do you?

MR. ORENT: Objection.

THE WITNESS: Yeah. Again the degree of the symptoms would depend on many factors. I can say that this picture shows that there was a degree of compression of the muscle.

BY MR. THOMAS:

Q. Can you say from this slide, that there was urinary dysfunction based upon this slide?

A. Complete obstruction of the

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urinary outflow, no, I cannot say that. I mean there is interference, but the degree of it is more complex question.

Q. Page 45, Figure Set 8b is the same issue using a smooth muscle actin stain. And because this is additional TVT cases, this is going to be a different patient than 8a, correct?

A. That's correct.

Q. Is this a TVT or a TVT-O?

A. I cannot say.

Q. And is this the smooth muscle stain that you referred to a few minutes ago?

A. That's correct.

Q. And what does the stain in Figure Set 8b tell you?

A. So you can see clearly that the smooth muscle is in wisps. So this is the smooth muscle of vaginal wall, and it became incorporated into the mesh.

So the mesh migrated in the tissue, and this part of smooth muscle became incorporated in the mesh pore.

Q. How can you tell from Figure 8b that the mesh migrated or moved?

A. Because it contains normal structure.

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Q. How does this figure -- how are you able to tell from this figure that the mesh wasn't placed there in the first place, as opposed to migrated or moved there?

A. This space didn't exist before the mesh was placed (indicating).

Q. Okay. And "this space" is what you just drew as a circle?

A. Yes.

Q. And what does that space represent?

A. It's the space within the mesh. So it was created in the body, when the mesh was placed. When the mesh was placed, it's empty space because tissue is disrupted. The mesh goes in, and everything inside needs to be filled in with brand new tissue. So this area was filled with tissue after the mesh was placed.

But, we know that smooth muscle is a more specialized type of tissue. It has very limited ability for regeneration, so the scar which can be produced. So if there is normal tissue within the mesh pore, it means that it had been incorporated later on, either through scar contraction, which pulls normal tissue in, or through mesh migration, which migrates into this

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(indicating).

Q. What types of symptoms are present from the findings that you have in Figure Set 8b?

A. I don't remember exact history for this specific patient, but this position of smooth muscle inside the mesh, is at risk for pain, especially during intercourse, dyspareunia. Again, the degree of these symptoms is difficult to predict. But this is an abnormal position of smooth muscle.

Q. Are you suggesting that every time this patient would have sexual intercourse, that she experienced pain due to this condition?

MR. ORENT: Objection.

THE WITNESS: How much of this will contribute to her symptoms would be difficult to predict. But as I said, this is an abnormal position, and this abnormality provides a risk factor for pain during intercourse.

BY MR. THOMAS:

Q. Okay.

A. Or just simply chronic pain.

Q. So as we've talked about before, this is a risk factor in conjunction with other things that may cause the conditions you're talking

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about?

A. That's correct.

Q. Anything else remarkable about 45?

A. No.

Q. 46, Figure Set 8c.

Again, this is more smooth muscle with smooth muscle actin stain, additional TVT cases. Is this a third patient, do you know?

A. This is an older case.

Q. So is this a third patient within this set?

A. Most likely.

Q. And it's an older case given the camera that's used?

A. Yes.

Q. Can you tell whether it's a TVT or TVT-O?

A. No.

Q. What is the significance of Figure 8c?

A. This is a nice picture, this is urethral wall.

Q. You're talking about the muscle on the right side of the image on the left?

A. Yup.

Q. Okay.

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A. It's a thicker bundles of urethra, and this part is vaginal wall. So this is part of vaginal wall. And you can see the curve of the sling was compressing urethra (indicating).

So this part of the sling was excised with some of the urethral muscle.

Q. What is the significance of this finding in this figure?

A. It shows the difference between smooth muscle in the vaginal wall and smooth muscle in the urethra, and the relationship of the mesh, how it sits right on the muscle of the urethra.

Q. If you look at this, as it's going to be in-situ, is it going to look like this?

A. Eventually it will look like this.

Q. So this is the urethral muscle, and I'm holding Figure 8 sideways. So this shows how the mesh has either the U-shape or the hammock shape underneath the urethra; correct?

A. That is correct.

Q. Okay. So the positioning of this mesh is really consistent with the way it should be placed; is that correct?

A. It's the normal position. It's not normal, intended position.

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Q. Intended position, okay.
So what is significant about Figure 8c, insofar as it relates to your opinions in this case?
A. Well, I'm demonstrating that the mesh is compressing right against urethra. And if it was more pressure, it would start migrating into urethra and sometimes I see that as well.
Q. When you say migrating, are you talking about eroding into the urethra?
A. Yes.
Q. Okay. There's no evidence here, though, of evidence of erosion into the urethra, correct?
A. In this specific case, I don't remember.
Q. Well, you don't see it in the slide. You can't offer the opinion to a reasonable degree of medical certainty that this mesh has eroded into the urethra here, correct?
MR. ORENT: Objection.
THE WITNESS: Not in this image. And the purpose of this different.
So you can see clearly, I should have probably turned it. I should have turned it like

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this (indicating). And this would demonstrate that with more pressure, it would start migrating; in this specific case, it didn't.
BY MR. THOMAS:
Q. Isn't this supposed to be right underneath the urethra in order to control the urine flow?
A. Yes, but I mean --
Q. Is this not placed properly?
MR. ORENT: Objection.
THE WITNESS: I wouldn't go and I cannot testify exactly for placement.
To me, as a pathologist, I examine what is abnormal and what can cause symptoms.
So if there are specific requirements for placement or positioning, it would be a clinical question.
BY MR. THOMAS:
Q. Okay.
A. So to me, this position, right against smooth muscle of urethra, indicates that sling is compressing against urethra directly.
So, with extra pressure, you can collapse or compress urethra and cause urinary outflow. And this is repeated in medical histories

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that slings can cause urinary outflow and obstruction.
And with more pressure, it will start going through the muscle and become eroded. Also, it will describe the clinical phenomena.
Q. And when you talk about disrupting urinary outflow, is that the same thing as retention?
A. Yes.
Q. And that's a recognized complication from mesh placement?
A. Yes, it is.
Q. Anything else remarkable about this slide?
MR. ORENT: Objection.
THE WITNESS: No.
BY MR. THOMAS:
Q. Is it fair to understand that you're not able to diagnose urinary retention based upon this single slide, correct?
A. Retention is a symptom, as we've discussed before, symptoms are caused by multiple factors together, so...
Q. Answer my question. Based on this slide alone, you can't make that finding?

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A. You can say that this position creates a risk for obstruction.
Q. Yeah.
A. And a degree of compression of the urethra.
Q. But like everything else, that's a risk factor that you'd have to combine with other things to determine whether, and to what extent this could cause any problems in her, right?
MR. ORENT: Objection.
THE WITNESS: Not necessarily. It may not need other factors. It may cause symptom on its own. But the degree of the symptom is clinical presentation.
BY MR. THOMAS:
Q. And you don't know what that clinical presentation is as you sit here today?
A. That's correct.
Q. Page 47, Figure 8d. This is, "Innervation within the mesh and between the mucosa and the mesh. Also, images of muscle movement involvement by the mesh." And this is a publication?
A. That's correct.
Q. Do you know what kinds of mesh are

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involved here?
A. I don't remember. I think two of these images are from TVT or TVT-O. And two of these images are from different mesh.
Q. Which ones are from TVT or TVT-O?
A. I don't remember now. I would have to sort of do matching.
Q. Okay. What other manufacturers did you look at?
A. AMS, Boston Scientific, Bard.
Q. And do you know which of those manufacturers are depicted in this image?
A. No, I know for sure that there's at least one TVT mesh here.
Q. At least one?
A. At least one. I don't remember --
Q. Do you know whether it was a TVT or a TVT-O?
A. No.
Q. Okay. And what is the purpose of this image?
A. It demonstrates same smooth muscle involvement.
Q. Are you able to tell -- as I understand the smooth muscle is either going to be

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in the vagina or around the urethra, correct?
A. That's correct.
Q. Are you able to tell in Figure 8 whether this is the vagina or the urethra?
A. Let me see, because the pictures are cropped to a degree.
Q. They're "cropped", did you say?
A. Cropped, yes. So I need the larger pictures to -- let me see.
Maybe it's described in the caption. (Witness reviews document.)
Just representative image. From what I see, but it's not 100 percent, it may not be 100 percent correct.
C, would reflect urethral muscle. And D would reflect vaginal muscle. But I'm not sure, because most of the structures are cropped. It just describes the fact that the mesh can incorporate smooth muscle, from either origin.
Q. And just so we're clear. You're pretty sure that one of these is a TVT or a TVT-O, but you don't know which of the four figures in Figure Set 8d is a Johnson & Johnson product?
MR. ORENT: Objection.
THE WITNESS: It would be either these

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two or both (indicating).
BY MR. THOMAS:
Q. Okay. C and D, correct?
A. C and D. That is my recollection.
Q. What is it about those images that cause you to believe it's an Ethicon TVT or TVT-O?
A. Oh, maybe not. Wait a second. (Witness reviews document).
Sorry. I have to retry this. I don't remember which exactly are TVT or TVT-O. It could be one of these images in one of these.
Q. It could be any one of the four?
MR. ORENT: Objection.
THE WITNESS: Yes, I would have to go back and check.
BY MR. THOMAS:
Q. Now this is smooth muscle; is that what you're saying?
A. These are smooth muscle.
Q. In A, B, C and D?
A. No. Figure A shows neurovascular bundle in the pore, we saw similar images before that.
Figure B shows innervation between sling and mucosa.

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Figure C -- (witness reviews document.)
Q. Are you reading the text now?
A. Yes. So Figure C shows striated muscle.
And Figure D, shows smooth muscle unspecified, either from vagina or urethra.
Q. Okay. And is the purpose of this image just to show the innervation of the mesh in general?
A. Well, the purpose of the image is to show all these pictures together. And I included it because I knew that at least one contains TVT or TVT-O, it is a supplementary picture.
Q. Anything else significance for the figures on page 47?
A. No.
Q. Page 48, Figure Set 9a. "Arterial obliteration in the mesh scar plate, H&E 10 times. Consolidated cases."
This obviously is from one of the plaintiffs in the consolidated cases.
A. Yes.
Q. And you've indicated on the image an obliterated artery. How can you -- what is it

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about this image that tells you that this artery is obliterated?
A. The lumen is collapsed.
Q. The lumen is collapsed?
A. Yes. The arterial wall is degenerated, so clearly non-functional.
Q. And what does it mean to have an obliterated artery?
A. It means that there is an area in the body which had insufficient or disrupted blood supply.
Q. Okay. When you say "insufficient or disrupted", it can be disrupted without being insufficient; can't it?
A. That's correct. There might be a collateral circulation sufficient to supply.
Q. And you're not able to tell from looking at this image in Figure Set 9a, that if this is an obliterated artery, that it has any clinical impact on the patient, correct?
MR. ORENT: Objection.
THE WITNESS: Again, could have had only short-term impact, could have had longer term impact. Short term would be necrosis, right after the obliteration, or thrombosis, it's like heart

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attack.
And then long-term would be scarring and fibrosis. The same thing as a heart, people who have insufficient cardiac output. If heart muscle doesn't work as well as before the infarct, so the same thing here, it would be a short term, shortly symptoms or changes in the body. And then longer term. Longer term would be caused more fibrosis.
BY MR. THOMAS:
Q. And longer term there may or may not be a problem, correct?
A. You mean how they would translate into clinical symptoms?
Q. Yes.
A. The degree of translation into clinical symptoms is more a complex process.
Q. Okay. Is there necrosis in this image?
A. No. Because artery has supplied the blood to somewhere else further down, so...
Q. Okay. So given your finding of an obliterated artery, there are no clinical symptoms manifested in this image, at this time that you can point to, correct?

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MR. ORENT: Objection.
THE WITNESS: Not in this area.
BY MR. THOMAS:
Q. Okay.
A. But it tells us that somewhere else beyond this square picture, there was damage for the tissue.
Q. There was or may be?
A. There was.
Q. Okay.
A. The degree of it is difficult to determine. But there was.
Q. You'd have to see the tissue in order to make that evaluation, correct?
MR. ORENT: Objection.
THE WITNESS: Yes.
BY MR. THOMAS:
Q. Where is the mesh in Figure 9a?
A. Somewhere beyond it.
Q. It's not in the slide?
A. Maybe right at the corners, I don't know.
Q. But you didn't capture any mesh in the slide on 9a?
A. I didn't crop it in.

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Q. Let's go to page 49, Figure Set 9b.
A. Yes.
Q. It says, "Examples of capillary thrombosis in the mesh scar plate."
What is "capillary thrombosis"?
A. When there are small thrombi formed in the capillaries.
Q. What is the significance of capillary thrombosis in the mesh scar plate?
A. The same as for arteries, just on a small scale. So there's interruption of blood supply in the smaller area. Artery can cover large area, capillaries are covering small.
Q. Is there anything about what you see in Figure Set 9b, that would tell you that this patient is experiencing any clinical symptoms?
A. Again, the degree of manifestation of this finding would be difficult to determine.
Q. It could be nothing?
A. May not be clinically apparent.
Q. And is this a single plaintiff or is it two different plaintiffs? It says, "additional TVT cases." I can't tell if it's one patient or two.
A. I think it's from the same patient.

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Q. Is it a TVT or TVT-O?
A. I think it was the Edwards case. That's as far as I can recollect.
Q. Okay. Is there any mesh in Figure Set 9b?
A. Right there (indicating).
Q. So that's on the lower left, okay. Is there any mesh in the image above?
A. Not in the image. It was probably right beside it.
Q. Okay. Let's go to Figure Set 10a on page 50. It says, "TVT sling curled into a roll cross-section through parallel walls. H&E stain 2.5 power magnification. Consolidated cases." This shows a piece of curled mesh, doesn't it?
A. That is correct.
Q. And this is the curled mesh that you talked about before when you place it in formalin that it will curl over on itself, correct? When it's placed in formalin?
A. Did I say that it curls in formalin? I said that mesh, which is curled in scar tissue, curled in the body.
Q. I see. So you believe that this

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curled in the body?
A. Yes.
Q. And on what basis do you believe that?
A. Because that curl shape is immobilized within the scar tissue, it's incorporated in the scar tissue, in this shape.
Q. Okay. Anything other than the curling phenomena that you've just described as the purpose of Figure Set 10a?
A. Curling phenomena, scarring, it's all encased in scar tissue.
Q. Okay.
A. That's about it.
Q. Okay. And at the top where we see the blue, those are going to be artifacts?
A. No. The blue ones are cross-sections of the blue filaments.
Q. I should have said, in places where they don't fill the holes?
A. It can't be clear filament. Because remember, half of the fibers in the sling are blue, half of them are clear.
Q. Okay. Let's look at the top, off of the slide there is a blue fragment. That

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obviously has been pulled away from the slide, correct?
A. That's correct.
Q. That's polypropylene?
A. That's correct.
Q. Let's go to set 10b. Is set 10b from the same patient or a different patient?
A. I suspect it is the same patient.
Q. Do you know?
A. Not with 100 percent certainty. But I think it is. It's just a different part the of the same curled mesh.
Q. Okay. And does Figure Set 10b show anything new beyond what you've showed in 10a, or is it the same?
A. It's the same, just tighter roll.
Q. And if you look at the images at the top, there's a blue line coming out of the top right, and that's a polypropylene artifact?
A. Displaced polypropylene fibers. You can also see dilated vascular channels.
(Reporter sought clarification.)
A. So in this area, there is vascular dilation.
Q. Can you tell from these images,

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10a and 10b, whether this mesh caused any symptoms in the patient when it was implanted?
MR. ORENT: Objection.
THE WITNESS: My answer is the same. Clinical symptoms is a multifactorial, complex phenomena.
BY MR. THOMAS:
Q. This is a risk factor?
A. No, this is not a risk factor, this is a mechanism, how the complications occur.
But then there is a patient in between who feels the symptoms, and the body however reacts and so forth. But in this case, the mesh is rolled, so the pressure is distributed in a small area.
The probability that it will compress urethra is higher, because if it was flat, it would have much larger distribution of pressure.
Q. So is the risks from this curl mesh compression against the urethra and urinary retention?
A. Yes, one of those.
Q. Do you know whether this patient had urinary retention?
MR. ORENT: Objection.

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THE WITNESS: I don't remember now. Because my purpose for this report was to actually show these things which can happen, and the pathological changes which happen after mesh placement.

And, symptoms which can factor in.

BY MR. THOMAS:

Q. Okay.

A. But I wasn't working on specific connection between this pathological change, caused that symptom in this specific patient.

Q. Okay. Anything else remarkable about the images on 50 and 51?

A. No.

Q. Go to page 52. And you get "Neurovascular bundle within curled mesh, four times magnification. Consolidated cases."

Is this a different patient than was depicted in 10a and 10b?

A. One of these, because I say that it's curled mesh --

(Witness reviews document).

So likely it was one of these two.

Q. I think you told me -- well, maybe I didn't hear this right. I thought you told me

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that A and B were from the same person?

A. Most likely.

Q. Do you know?

A. I can tell you, but not right now. I can just check the name of the files.

Q. And do you think that 10c, is the same or different person?

A. Most likely it is the same person, or one of the two. It could all be from one patient, it could be from two patients.

Q. Okay. In the top part on 10c, on page 52, you have a displaced piece of polypropylene?

A. Yes.

Q. And what's the significance of identifying this neurovascular bundle in the figure?

A. As before, we were talking about entrapment of the neurovascular bundle before. But in this case, it's not just in pore. It goes in the pore, and became entrapped in the curls.

So it's in between two layers of the mesh right inside the curl. So it's secondary type of compartment. Because before we're talking about compartmentalizing nature of the mesh, and then we

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talk about flat mesh, it's sort of third dimension. So compartments are within the thickness of the mesh. But when it curls, it creates secondary compartment. Compartment which is encircled by the mesh or between the folds.

Q. Anything that you can see in Figure 10c, on page 52 that is abnormal or symptomatic about that neurovascular bundle, other than its presence in the scar tissue?

A. It's abnormal location.

Q. It's simply that, the abnormal location?

A. Yes.

Q. Anything else?

A. The surroundings are abnormal.

Q. Okay. Anything else remarkable about that image?

A. No.

Q. Let's go to page 53, section 10d. This is, "A twisted TVT sling" from additional TVT cases."

So this is one of your older cases, correct?

A. Yeah. Earlier or concurrent.

Q. Is this a TVT or TVT-O?

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A. I don't know.

Q. What is the significance of what you've done in Figure 10d?

A. It shows that the mesh just curled, and also twisted. To get the shape like this out of flat tape, it has to curl and then one end is twist.

Just think about it, how they put these sections in this shape. So one end like this, and the other one is probably like that (indicating). Or maybe like this (indicating).

Q. Okay. Does that happen by placement, or by migration in the body, or do you know?

A. It's hard to figure out if you can place it like this.

Q. Do you know?

A. I don't know. One thing I can tell you, this shape was formed in the body and then it became incorporated in scar tissue like this.

Q. But you don't know whether that happened on placement or in some other way?

A. No.

Q. Okay. Now, in Figure 2 and

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Figure 3, you show different images of the yellow. What's the purpose of doing gradations of the yellow?

A. Well, this shows the planes of the mesh. Just to help you to understand that we're talking about the mesh which twisted.

Q. Okay. Figure 10e is explanted mesh. This has been in formalin, correct?

A. Yes. I believe it was in formalin.

Q. Okay. And no attempt to clean it at all, correct?

A. That is correct.

Q. And the purpose here is to show what you believe to be the curling of the mesh?

A. Well, it's not what I believe. I observe curling. It's hard to show in the picture, but when you look at it with just magnifying glass or if you have good eyes, you can see that the mesh is curled up and then it's all filled with scar tissue.

Q. Is the purpose of this just to show the simple curling, or are you trying to show something beyond other than that?

A. No, just curling. And that the

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curled shape is actually filled with scar tissue. It's not formalin, as you'd like to say, causing the curling. It was removed from the body in that shape.

Q. Can you tell whether, assuming this is curled in the body, whether it was curled upon placement or curled after placement?

A. The only thing I can say, it can happen, and it happened.

Q. Okay. But you don't know whether it happened during placement or after placement?

MR. ORENT: Objection.

THE WITNESS: I don't know.

BY MR. THOMAS:

Q. If you go to page 55, Figures A and B, set 10f. "A TVT sling with curled edges. Right sling is TVT."

Are these two different slings or one; do you know?

A. These are two different slings, this is AMS, this one I remember.

Q. AMS is on the left?

A. Yes.

Q. And TVT is on the right?

A. Yes.

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Q. Is it TVT or TVT-O?

A. I don't know.

Q. Does the AMS figure have any relevance to your discussion in this case?

A. Not necessarily, no.

Q. Okay. Tell me what is significant to you about the TVT in part B of set 10f?

A. See, the images which were taken from publications were not cropped, so I don't remove any panels. So in this image, I think I had a TVT, I provided the entire --

Q. I understand, that's okay.

A. So in this case I can tell exactly this is TVT, and this is a different manufacturer.

Q. All right. So what is the significance of slide B?

A. It's curled, it's roped. You can see it's not tightly -- it's not flat. It's tightly curled.

Q. Can you tell whether it was placed that way or whether that happened after placement?

MR. ORENT: Objection.

THE WITNESS: I can't say. The only thing I can say is that it happened in the body.

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BY MR. THOMAS:

Q. Okay. Anything else remarkable about 10f on page 55?

A. No, just roping.

Q. Page 56, you have Figure Set 10f again. Is that a typo, or is that the same mesh? It looks like a different mesh, it looks like one of yours.

A. It's a typo.

Q. So this would be 10f --

A. No, it should be 10d.

Q. 10d?

A. I think it's the same specimen as 10e.

Q. Okay.

A. The same case, I believe. So this case took two pieces. One piece was rolled like this, like 10e.

Q. Okay.

A. And the second piece was flat area. Sometimes one piece, especially if it's heat-treated doesn't curl. So there is a segment of mesh --

Q. What do you mean heat-treated, during removal?

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A. No, during manufacturing.
Q. Are you talking about heat-treated as in laser cut?
A. No, the entire surface is heat-treated, not just edges.
Q. And so what impact -- I didn't see it anywhere in your report, that heat somehow in the manufacturing process will impact the ability of the mesh to lay flat in the body?
A. It doesn't curl -- oh, doesn't curl as much.
Q. Okay.
A. It's more stable structure because fibers are welded together, or to a degree connected together.
Q. Okay.
A. I know that some of the tapes --
Q. Some other manufacturers?
A. Other manufacturers, middle portion is heat-treated.
Q. Okay. So did Boston Scientific mention it?
A. I don' know.
Q. It's all right.
A. I don't remember now. I mean some

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of them were coming out first, with no heat treatment, and then later on they became heat-treated.
So some portions don't curl because of heat treatment, or just don't curl because of other factors. So in this specific case, there was a segment of the sling removed, and it was curled. And in another segment of the sling removed and it remained flat in the body.
Q. Okay. Do you know why?
A. No, I don't know. One of the reasons can be heat treatment.
Q. It could also be placement?
A. It could also be placement or location.
Q. And what is the purpose of the red and the yellow on the image on 10f on page 56?
A. It just demonstrates how flat section of the mesh looks, and how a curled section of the mesh looks. Because here, cross-section, this mesh.
Q. Yes?
A. And then it came on histological sections like this.
Q. Is this from a case, additional

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TVT cases?
A. Yes.
Q. Has this been produced in a report somewhere? I've never seen this image in a case anywhere, I'm just curious to know if it's been published in a report someplace.
A. I don't want to disclose that if it has not been produced, so it have been produced.
Q. Let me ask you this. Here is why I ask: Generally, as you know, at least with Ethicon, we divide these meshes before any work is done on them.
Did you divide this mesh with Ethicon before you did this work on 10f?
A. It could be that was divided with your expert, so we were taking pictures together.
Q. Okay. Well maybe that's right.
A. I think it was the case. Now I can vaguely remember the issue because we were discussing how we're going to cut this diagonal or cut it --
Q. I see.
A. And so I remember him standing beside me, and I was taking those pictures.
Q. I see.

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A. I took this picture, then this picture, then we probably have similar pictures from him.
Q. And I apologize, I've been asking this question a lot, and I don't know if I've asked you about this slide, so if I have, I apologize.
You don't know whether the curling depicted in 10f, on page 56 occurred during placement or after placement, do you?
A. No, I don't.
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Page 57, Figure Set 10g. "A TVT sling with curled edges." Is this a different TVT than the ones we've looked at?
A. I think these are the pictures of the same case. Again, that is my recollection, I'm not 100 percent sure, but I think.
Q. Do you know if this is a TVT or a TVT-O?
A. No.
Q. Are you trying to show anything by these images on 10g other than a different depiction of what's in 10f?
A. Well, no. This just shows the

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curling state, this cross-section (indicating).

Q. Okay. So it's your best recollection that the images in 10e, 10f and 10g, are from the same mesh, same patient?

A. Yes, likely than not, these are all from the same patient.

Q. But you're not sure?

A. No. As I said, the purpose of this report was to analyze the device as a whole, not the individual patients.

Q. 10h: "TVT sling with curled edges. Additional TVT cases"?

A. Yes.

Q. Do you know where -- is this a new patient; do you know?

A. It's older pictures, taken by old camera.

Q. Do you know whether this is a TVT or TVT-O?

A. No.

Q. What is the purpose of this image?

A. It show the cross-section of the curl. And you can see it clearly, the whole field is scar tissue. This indicates that this curl shape was formed in the body and then the scar

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tissue growing inside and filled the two-block structure.

Q. And are you able to tell from this image, whether it was curled on placement or curled after placement?

MR. ORENT: Objection.

THE WITNESS: No.

BY MR. THOMAS:

Q. Anything else remarkable about Figure Set 10h?

A. No. Curling, scar encapsulation, scar filling.

Q. Page 59, Figure Set 10i: "Neurovascular bundle with rolled TVT tape, S100 stain. Additional TVT cases."

Is this from the same or a different patient as set 10h?

A. I don't remember now.

Q. Do you know if it's a TVT or TVT-O?

A. No.

Q. What are you trying to show in Figure 10h?

A. It's a single picture for single purpose as 10c, on page 52. A neurovascular bundle

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is inside the roll of the curled tape.

Q. And is there anything about the depiction in the neurovascular bundle in set 10i on page 59 that is irregular or abnormal other than its presence in the scar plate?

A. Well, it's bent by the mesh fiber, you can see clearly that it deviates from straight course.

Q. Anything about that that makes you have an opinion that this is causing any symptoms in the person who has this mesh?

MR. ORENT: Objection. Form.

THE WITNESS: Probably, the nerve is irritated by these fibers higher, because it is a direct compression on the nerve.

BY MR. THOMAS:

Q. But there's nothing about this slide, just like the other slides, which tells you that the neurovascular bundle in Figure Set 10i, actually caused symptoms in the person who had this mesh?

MR. ORENT: Objection.

THE WITNESS: We discuss this before. The degree of symptoms, the expression by the patient is a complex process.

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So I can say that this is abnormal, this is a mechanism for symptoms, and then that can happen.

BY MR. THOMAS:

Q. And the reason why you say it's abnormal is because the mesh fiber causes this bundle to alter its path?

A. Yes.

Q. Anything else?

A. No.

Q. Page 60.

A. Yes.

Q. Figure Set 10j: "A rolled TVT sling sectioned parallel and perpendicular to the roll. Additional TVT cases."

Do you know whether this is a TVT or TVT-O?

MR. ORENT: Objection.

THE WITNESS: No.

BY MR. THOMAS:

Q. What is the significance of this slide to show what you showed in previous slides. That is, the fact of the curling?

A. Fact of the curling and mechanism for erosion on page 61, I demonstrate how the

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erosion occurred. Because one end of this curled tape became eroded.

Q. Okay. So this is, the dark end of the tape on page 60 and on 61, it is in fact an erosion?

A. Yes, it's --

Q. Where did it erode?

A. In the mucosa, in vaginal mucosa.

Q. Did it erode into another organ?

A. No, it eroded through the mucosa into the vagina.

Q. Do you distinguish between an erosion and an exposure?

A. Technically, there is a distinction. The terms are used interchangeably, so there is no agreement which one is --

Q. Let's use the technical terms, just so you and are communicating. Is this an erosion or an exposure?

A. Both.

Q. Okay.

A. Because the mucosa eroded on top of it and mesh became exposed.

Q. Okay. But in terms of the mesh going into or eroding into another organ, that

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didn't happen here?

A. Well, it eroded into the mucosa.

Q. Okay. But just the mucosa, not the bladder, not the rectum?

A. Not the organs. Because it is a different location.

Q. All right. And do you remember this patient?

A. No.

Q. Do you know how this patient was treated?

A. By sling excision.

Q. Do you know how it worked out? How she recovered from the excision?

A. Better that she didn't have eroded mesh anymore after surgery. Maybe it eroded again in a different place.

Q. Do you know whether she experienced pain as a part of this?

A. Most likely she did.

Q. Do you know whether she experienced pain as part of this?

A. The degree of pain, as I said, I don't remember now. But most likely she did.

Q. You have not consulted her records

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to see the extent to which this was a painful experience for her?

A. This is commonsense. This is a chronic and open wound; would it hurt? Of course it would.

Q. Go to page 61. Figure Set 11b. Is this the same mesh?

A. No, it's a different one.

Q. All right. Is this a TVT or a TVT-O?

A. I don't know.

Q. And what are you trying to show in Figure Set 11b?

A. Similar mechanism for erosion, the mesh somehow rotated, probably through curling of the edges and then became exposed. The edge pierced through the mucosa.

Q. And this is an erosion, as you've defined it, in the last section, some people may call it an exposure, correct?

A. Yes. It's called -- if you want to call exposure, we will call it exposure. So the mesh became exposed.

Q. And what does the mesh in this tissue sample tell you?

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A. The position, see the position is towards the mucosa. So it's not bilateral to the mucosa, it's angled. And the edge, or the end of the tape became exposed, pierced through the mucosa. And the site of exposure became infected and now there is acute inflammation surrounding.

Q. How do you know that this mesh was infected?

A. Because there is acute inflammation in there.

Q. Do you know how long this woman had this sling before it was removed?

A. I don't remember.

Q. Are you able to tell from this slide whether this mesh was placed this way or whether it changed after it was placed?

A. It's hard to place it like this, because you can see it's clearly perpendicular. So I just cannot imagine it.

Q. Do you know?

MR. ORENT: Objection.

THE WITNESS: I don't know for sure, but this would be a really difficult position to achieve during placement.

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BY MR. THOMAS:

Q. Anything else remarkable about your description of set 11b?

A. No, we discussed most of it.

Q. Anything else you want to talk about? You said "most".

A. Sorry.

Q. Page 63, Figure Set 11c: "Exposed edge of TVT sling rotated towards the mucosa. Additional TVT cases".

Do you know whether this is a TVT or TVT-O?

A. No, I don't.

Q. And what is your purpose of including Figure Set 11c?

A. Just mechanism of exposure, because the edge is pointing towards mucosa.

So it's a near exposed position in this case. Probably exposure occurred somewhere either more superficial, or deeper in the block.

Q. As you're looking at that mesh, is the mesh -- you show the yellow portion of the mesh going from the bottom of the figure to the top of the figure. Is that the width of the mesh?

A. With the length, it's very hard to

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determine in this place. So the mesh is either in this shape (indicating), or this shape (indicating).

In any case, one of the edges is pointing towards mucosa.

Q. When you talk about -- strike that. This mesh when placed, is going to stretch from one side of the abdomen to the other, isn't it?

A. Yes. But we are talking about mucosa. So it is a very short stretch of the mesh right where it goes between the urethra and vaginal wall.

Q. I understand that. But my point is, the only thing that can be exposed there is the midpoint, not the ends, correct?

A. Unless you cut one end, and then it becomes exposed again.

Q. Okay. And in order to cut the end, you'd have to cut the end at the vaginal mucosa, correct?

A. Inside. So what happens -- first exposure occurs, it curls up like this. So this part is exposed, there is a revision surgery, one end is cut, the patient is left and sometimes it

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curls up like this.

Q. Is this a multiple revision?

A. I don't know.

Q. You don't know?

A. (Witness nods.)

Q. Okay. For the other mesh erosions, or exposures that you've discussed on 58, 59, 60, 61, 62 and now 63, do you know whether those are first revision cases, second revision cases, or multiple revision cases?

MR. ORENT: Objection.

THE WITNESS: I don't remember exactly. Sometimes it's first revision, sometimes five, six revisions.

BY MR. THOMAS:

Q. You just don't know?

MR. ORENT: Objection.

THE WITNESS: If I go through records, if it was individual report of a case, I go through records thoroughly, so I know exactly how many revisions it was.

BY MR. THOMAS:

Q. Go to page 64. Figure Set 11b, is that part of Figure Set 11c, or is that different?

A. No, it's different.

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Q. How can you tell?

A. It's a different slide.

Q. Okay. Is it a different patient?

A. I don't remember.

Q. Okay.

A. It may or may not be.

Q. Okay. Do you know if it's TVT or TVT-O?

A. No.

Q. Page 65, Figure Set 11e; isn't that the same as Figure Set 11c?

A. I just noticed, something happened.

Q. You liked that one?

A. Could have been pasted twice or selected and pasted -- I don't remember. Something happened here. So I probably intended to insert different picture, but this one made it.

Q. Okay. I think we can say that 63 and 65 came from the same patient?

A. Yes. It just shows you that I don't have an army of people helping me, I'm just alone.

Q. I understand. Let's go to page 66, Figure Set 12.

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A. Yes.
Q. This is additional TVT cases. Do you know whether this is a single mesh or multiple meshes?
A. What do you mean a single mesh --
Q. There are four frames here. Excuse me, there are two frames here.
Do you know if it's the same one patient or two?
A. No.
Q. You don't know whether it's one or two?
A. No.
Q. Do you know whether it's TVT or TVT-O?
A. No.
Q. What are you trying to show in the top image on page 66, Figure Set 12.
A. Acute inflammation at the site of exposure.
Q. When you say acute inflammation, is that different from infection?
A. No. Acute inflammation is reaction to infection. Technically, it's the same pathological process.

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Q. I was just going to ask you that. Can you diagnose infection from this slide?
A. Yes, I can.
Q. And based on what?
A. Based on the acute inflammation.
Q. Okay. And what is it about the slide that shows the acute inflammation?
A. The neutrophils.
Q. And the slide below that, again, shows acute inflammation, and that may or may not be the same patient?
A. That's correct. I have feeling that they are different patients. I think one of -- the top one is the later case, the bottom one is an earlier case.
Q. As you sit here, do you know which ones they are?
A. The quality of the histology and the quality of the picture.
Q. In the top image, where you show the acute inflammation, is there mesh in that image?
A. Underneath, if you go a little bit over.
Q. This doesn't appear in the image, correct?
A. You're correct.
Q. Thank you. And in the lower image on Figure Set 12, the yellow represents polypropylene?
A. That is correct.
Q. And the presence of neutrophils again shows the acute inflammation?
A. That's correct.
Q. Anything else remarkable about that slide?
A. No.
MR. THOMAS: I need to take a break, please.
-- RECESS AT 3:19 --
-- UPON RESUMING AT 3:23 --
BY MR. THOMAS:
Q. Doctor, I understand from prior depositions that when you analyzed your medical-legal cases that you prepared your own, for lack of a better description, your own pathology report. I think you called it a synoptic recording for each of the plaintiffs?
A. Not for medical-legal. I do it for all mesh cases, it's a part of research.

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Q. Do you have those kinds of recordings for all of the patients that are in your report?
MR. ORENT: Objection.
THE WITNESS: May or may not. Probably I don't have for all patients. Some cases are probably not even signed out, so the report is not completed yet.
BY MR. THOMAS:
Q. I guess my point is that we didn't get any of those on your thumb drive. And I'm curious if there's some of those that we don't have. We have a lot of them in the Huskey, Edwards case or the Bellew case -- in the Bellew case, you produced those to us for the --
A. Yes. When I started doing my research, I realized that I needed more or less standardized approach when I examined the meshes.
And I started entering them as a synoptic report, which is a specific pre-set number of parameters, so I don't forget and they're all analyzed in the same manner so they can compare them. It has nothing to do with medical-legal cases, or nothing else. It's pure documentation for research purposes.

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Q. Do you have that for each of the slides that are in this report?
A. As I said --
MR. ORENT: Objection.
THE WITNESS: -- I don't have all of these patients, some of the reports are not finalized.
BY MR. THOMAS:
Q. I'm going to ask you to produce those that you do have.
I have a --
A. If it's medical-legal case and you're entitled to see the information.
Q. Okay. I have a title of a study, we talked before about your chemical oxidation study you were performing, and I asked you about the recipe for the chemicals to which you're exposing the TVTs to.
A. You mean hydrogen peroxide with chromium salt catalyst?
Q. Yes.
A. Okay. I remember.
Q. And there was a study we found called, "Controlled Peroxide Degradation of Polypropylene - Rheological Properties and

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Prediction of MWD From Rheological Data". Lead author, Azizi, A-Z-I-Z-I. Including I. Ghasemi, G-H-A-S-E-M-I, and M. KARRABI, K-A-R-R-A-B-I; does that ring a bell?
MR. ORENT: Objection.
THE WITNESS: You're asking the wrong person, I'm really bad with names. I'm a pathologist, I remember the slides but I don't remember the names.
BY MR. THOMAS:
Q. Do you have the study that you used to come up with the recipe?
A. Yes, I do. I can find it in my hard drive, and I can find it.
Q. Okay. Good.
A. It's most likely at least in the reference materials as well.
Q. In the reference materials to your report?
A. Yes.
Q. Okay. How did you determine which of the slides from your total number of TVT-O and TVT cases to include in the report?
A. I went to features. So every time I would be describing a specific feature in the

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opinions, I would go back in my pool of images, for TVT and TVT-O cases, and search for best images representing that specific feature.
Q. I see. So when you say "best images", you went back through about 100 different TVTs and TVT-Os did you say?
A. No, I said slings.
Q. I'm sorry. How many TVTs and TVT-Os have you looked at?
A. Ballpark of 30 to 40.
Q. Okay. And so you went back through your 30 to 40 to identify those that best represented the features that you wanted to show?
A. Images.
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Okay. Images?
A. I didn't take new images of various cases, I just used those images which were taken already. The only new images that I produced are the cases I received as a consulting trial set.
(Reporter sought clarification.)
A. Trial set, as a set to facilitate at trial.
Q. Let's go to Exhibit No. 2.

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Exhibit No. 2 is your supplemental report served two days ago.
A. Yes.
Q. And when you received this, you received slides from CAMC?
A. Yes.
Q. You didn't create your own slides?
A. No, I did the staining.
(Reporter sought clarification.)
A. My lab did staining.
Q. Do you know whether this is a TVT or a TVT-O?
A. No, I don't remember now.
Q. Okay.
A. I didn't review any medical records for the consolidated trial cases.
Q. And if you look at -- your pages aren't numbered, but the first image, which is identified as supplemental Figure EM1, it says: "Portion of excised mucosa with underlying mesh, H&E magnification equivalent to 1.6X objective".
What is the significance of this image?
A. It's just from my review showing where the mesh is and how it relates to the mucosa.
Q. Is there anything significant

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about this image in terms of risk factors or issues related to symptoms, clinical symptoms?

A. Well, it's close. So it's an overview of the part which didn't get exposed but it shows the proximity. You know, that's significant.

Q. And again, you don't know whether that was placed there or if it migrated there after placement, correct?

MR. ORENT: Objection.

THE WITNESS: That's correct.

BY MR. THOMAS:

Q. Okay. Anything else remarkable about supplemental Figure EM1?

A. No, there's scar tissue which encapsulates and fills the pore; that's about it.

Q. Okay. Supplemental Figure EM2. Is this part of the same slide or is this a different slide?

A. Oh, it's the same block.

Q. Got it.

A. Yeah, I think it's the same slide because I had only one H&E slide.

Q. It says in the first page you received unstained histological slides, plural.

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Did you only have one?

A. For H&E, I stain only one slide. So one slide was stained by H&E method, one slide smooth muscle actin, and one slide S100 protein.

Q. Okay. So supplemental Figure EM2 is just more of a magnification of Figure EM1, correct?

A. Yes, I think you can match it, it's from here.

Q. And again, what you're trying to show is the foreign body reaction and inflammation?

A. That is correct.

Q. Where is the bark in this image?

A. Which image? The EM2?

Q. Yes.

A. Maybe out of focus, maybe not there.

Q. Okay. If you go to supplemental Figure EM3, this is another portion of the same image, correct?

A. I think it's a different fragment, from the same slide but from a different piece of tissue. There were several pieces of tissue on the slide.

Q. I see. And what is the purpose of

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showing supplemental Figure EM3?

A. Again, shows mucosa and proximity of the mesh to mucosa. There is less than a half millimeter between the mesh and mucosa.

Q. What is the distance between those two mesh fibers that are shown there?

A. About a millimeter.

Q. Okay. Supplemental Figure EM4, again, you're showing the foreign body inflammatory reaction?

A. That's correct.

Q. If you go to supplemental Figure EM5?

A. Yes.

Q. You indicate in the description, "acute inflammation and indication of mesh erosion and bacterial infection".

Do you know whether this patient was diagnosed with an infection?

A. No, I didn't read the records. I can see clearly there is bacterial infection triggering acute inflammation. If they saw it clinically or they didn't, I don't know. But even if they didn't, I would tell them there was an infection.

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Q. Okay. Are you able to tell from these images that there was in fact a mesh erosion or mesh exposure?

A. Yes.

Q. And how can you tell that?

A. There was a breakdown of mucosa and entry for infection. That's why I can see acute inflammation.

Q. Where is the breakdown of the mucosa?

A. I don't know. It didn't get in the section.

Q. Are you assuming there's a breakdown of mucosa? You don't show one on the slide, correct?

A. It's not an assumption. I can tell you with 100 percent certainty that there was a breakdown in the mucosa. Because if mucosa is not broken down, there is no bacterial insemination and acute inflammation.

Q. Supplemental Figure EM6, you identify an obliterated artery?

A. That is correct.

Q. Anything remarkable about that finding beyond what we've talked about before, the

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other obliterated artery?
A. No. Exactly the same finding; interrupted blood supply.
Q. Which may or may not have clinical significance?
MR. ORENT: Objection.
THE WITNESS: The degree of the changes may or may not be clinically apparent.
BY MR. THOMAS:
Q. Okay. Because if the blood flow is reduced or interrupted, they may receive blood flow from other sources that would vascularize this area?
A. Yes. And then that was fibrosis, and then you mix up fibrosis which is caused by the mesh, then fibrosis lead to ischemia.
It's a complex setting; how much of that would translate from one specific symptom would be difficult to discern.
Q. Obliteration of arteries is a risk in any surgery of the pelvic floor, isn't it?
MR. ORENT: Objection.
THE WITNESS: Yes, there would be a risk for obliterated artery. But when you say obliterated artery in the tissue, which is not

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changed otherwise, because to obliterate an artery during surgery, you have to transect it.
So by the time of mesh placement, this part would be separated. So this is an intact structure, which was not transected during surgery. It became obliterated later on.
BY MR. THOMAS:
Q. If you go to supplemental -- how can you tell that it happened after placement?
A. It's not transected during surgery.
Q. I see.
A. See how are the arteries being damaged --
Q. I understand.
A. -- they get transected.
Q. I understand. Supplemental Figure EM7a, "innervation of the scar tissue encapsulating the mesh, S100". What are you showing in EM7a?
A. Nerve branch. EM7a and 7b is the same image; 7b is labeled copy of 7a.
Q. Okay. And the arrows are pointing to what?
A. Nerve branches, or nerves.
Q. And for the nerve and nerve branch

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on the upper right-hand corner, how far is that from the mesh?
A. This one is --
Q. I'm talking about this one, upper right?
A. Oh, this one. See, with this one I don't even know. Maybe there is fiber right there, so it's pinching it.
Q. Do you know whether that's fiber or not?
A. That is hard to determine, I suspect there is, but I wasn't sure therefore I didn't put it.
Now, looking at this image, I think there was a fiber. So that curvilinear shape is actually fiber compressing.
Q. How do you know that without looking at it?
A. Well, there's density, increased density. Similar to this area, the collagen is compacted right around the fibers.
Q. The tissue itself is pretty irregular, isn't it?
A. Well, see, this is clearly not the place where mesh fiber was. Because there is no

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capsule. If you look here, there is a capsule around the fiber, and if you look there, there is a capsule around the fiber. So I suspect there was a fiber here.
Q. Okay.
A. Not here, but there.
Q. Looking at those nerves, is there anything about the appearance of those nerves on light microscopy that suggests to you they were causing pain to the patient while the mesh was in place?
A. Could you repeat the question. I'm getting tired, sorry.
MR. THOMAS: Would you repeat it for me, please?
-- REPORTER'S NOTE: Question read back as recorded above.
THE WITNESS: They're healthy nerves which can conduct pain. This is one of the main findings.
BY MR. THOMAS:
Q. Okay. But again, there's nothing about those that allow you to state that those nerves were in fact reacting in a way to cause pain in a patient while the mesh was implanted?

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A. The point of the picture is to show that that tissue is sensitive, so it can sense pain.

Those nerve branches are not directly affected or at least one may, but the others are not directly affected by the mesh.

The point is that tissue around it is innervated, so if you get a formation, if you get distortion, mechanical compression, then it can sense pain.

Q. Okay. Page 67 of your first report, Figure Set 13a, you're talking about the Prolene degradation layer.

Do you know if this is TVT or TVT-O?

A. No.

Q. Do you know from what case this comes?

MR. ORENT: Objection.

THE WITNESS: One of the consolidated cases.

It's so similar to this study, which I think our scientists did in 87. I mean, even the arrow there is so similar.

BY MR. THOMAS:

Q. So all of these images are from

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the consolidated cases through 72, and our experts have these images, correct?

A. Images -- they have slides.

Q. Slides, that's what I meant.

A. Yes.

Q. I've talked to you, you've been talked to at length about these images in prior cases. Is there anything new and different about what's expressed in these images that you haven't seen before?

A. It is exactly what I described in the published papers and previous reports. Exactly all, everything is the same.

Q. For the other cases that you begin on 73, you had images from additional TVT cases. Do you know whether those are TVT or TVT-O?

A. No.

MR. ORENT: Objection.

BY MR. THOMAS:

Q. If you go to page 72, please?

A. Yes.

Q. On page 72, you show an empty space of detached core on the right image. And a separated degradation bark. The empty space means that the polypropylene dropped out of the image?

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A. Not image, slide.

Q. Slide, I'm sorry. Thank you.

A. It came detached and displaced.

Q. Okay. And left what you have described as the bark behind?

A. Yes, that's correct.

Q. All right. Now, if you go to the next page, page 73, again, additional TVT cases you show an image where you show the polypropylene still in place, correct?

A. Yes. So now there is a separation. The core separated from the bark, but the core didn't detach completely and floated away. It's still close, but there was a split.

Q. And this is detached as a part of the sample preparation process, correct?

MR. ORENT: Objection.

THE WITNESS: I don't know when it became detached. During surgery or during sectioning or during processing of the specimen.

BY MR. THOMAS:

Q. Didn't happen in vivo, didn't happen in the body?

A. No. I suspect it doesn't happen that often. I very rarely see the bark actually in

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the tissue, being displaced in the tissue away from the fibers.

Q. Have you studied how mechanically that happens?

A. It just breaks off. There is a shear force, a breaking force.

Q. When you say a shear force, does it shear off at the point where -- at about five microns as the degradation ceases?

A. It shears off in the interface between degraded and non-degraded.

Q. That's my point. Let's see if we can agree with this. We're dealing with visual observations here, correct?

A. Yes, that's correct.

Q. And is it fair to understand with respect to the images on page 73, where you show detached core and degradation bark separated, are you telling me that the detached core no longer has a bark on it?

A. They have a really thin layer of degraded material. Because the bark itself is not uniform. There is a higher degree of degradation on the outside and then smaller, smaller, smaller, smaller, smaller.

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Q. Right.
A. And then the degradation blends into not degraded polypropylene.
Q. Right.
A. So at certain point these micro cracks, and mono cracks, they cannot go into this completely solid material, so it shears off somewhere there.
I don't know if it's right at the end of them, close to them or how far they are. So there might be a layer of degraded polypropylene on the core. How thick it is, I wouldn't know.
Q. It's too small to measure by your technique?
A. That's correct.
Q. And your best estimate is that the degradation bark that appears, as you've described it in 73, is much as five microns?
A. This is thinner. By looking at it, it is around two microns.
Q. Now what you show on page 75, again from additional TVT cases, are the cracks which you believe to be oxidized polypropylene, correct?
A. I don't believe -- I know.

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Q. Okay. And Figure Set 13i, do you know if this is a TVT or TVT-O?
A. No.
Q. Do you know how long this was in the body?
A. Certainly more than a year.
Q. Why do you say that?
A. It's relatively thick. So if I check here where it's less tangential, this is the thickness, so it's definitely more than a year.
Q. When you devised your experiment to intentionally oxidize polypropylene, did you look at any methods that would allow you to intentionally oxidize polypropylene in a time of less than a year and a half?
A. No, I didn't take them out.
Q. You misunderstood my question.
Did you attempt to identify any kind of chemical recipe that would allow you to intentionally oxidize Prolene more quickly than a year and a half?
A. No.
Q. Why not?
A. I'm busy enough with other things.
Q. Okay.

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A. And I figure I just leave it long enough, soon enough it will form and I will see which would -- in which fluid the bark is thicker.
Q. We talked before, I believe at trial, about xylene and that you were conducting a test to determine the extent to which xylene impacted Prolene polypropylene; do you remember that?
A. Yes, I do.
Q. You told me, I believe, that you were currently testing xylene to determine whether xylene would impact Prolene polypropylene. Are you still conducting that test?
A. It's in the same set of jars. One of the jars contains xylene.
Q. Is that the only test that you're doing with xylene?
A. Well, previously I did testing for processing. So new mesh was put in regular xylene solution for time when it happens during tissue process.
Q. Did you produce that to me in the jump drive Exhibit 4.
A. No, these are the images of new pristine mesh. So this mesh had been through

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xylene.
Q. Okay. Did you do any other testing of pristine mesh impact on xylene over a period of time?
A. No. These only two. I did experiment for our routine processing, routine exposure to xylene, and then I started this experiment.
I was testing it within month or two after it became exposed. I was thinking maybe it would get dissolved; it didn't. But the long-term effect will be studied later on together with other solutions.
Q. When you put the pristine mesh through the sample preparation process, did you perform any analytical chemistry on the mesh to determine the extent to which xylene may have altered the chemical structure of polypropylene?
A. No.
Q. On page 84?
A. Yes.
Q. Is page 84 another image of what we had talked about at length on page 83?
A. No, this is a different case. This is a case consolidated case. This is

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appearance of case from -- you can see the name of the patient.

Q. Okay. So this is -- strike that.

Did you do any analysis for bark on the mesh depicted in Figure 16a?

A. It's embedded in histology. It's there. I mean --

Q. Have you ever done it?

A. I didn't do anything specific. It's embedded in histology. I can pull the slide and take picture of the bark.

But again, this is a St. Michael's patients, I'm not comfortable disclosing or giving pictures specifically for trial or anything else. I can tell you that I saw the bark.

Q. So, Figure 16b on page 84 is cracking on the surface of TVT mesh fibers. And this is from the consolidated cases for patient Dameron; is that correct?

A. That is correct.

Q. And these are the tissue samples that you show on 84 that you had available to you?

A. Yes.

Q. And they had been stored in formalin?

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A. No. We received it dry. Your expert was there.

Q. Okay.

A. It was jar without formalin.

Q. Do you know whether it was in formalin?

A. I don't. Probably it was at one time, it leaked out but... that's my assumption.

Q. You do know how long this was in the body?

A. No.

Q. And obviously you don't know how it was handled before it got to you, correct?

A. No.

EXHIBIT NO. 5: Study Entitled "Safety Considerations for Synthetic Sling Surgery" in which Dr. Vladimir Iakovlev appears as an author.

BY MR. THOMAS:

Q. Doctor, I'm going to hand you what's been marked as deposition Exhibit No. 5.

A. Yes.

Q. Deposition Exhibit No. 5 is a review study in which you appear as an author --

A. Yes.

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Q. -- entitled, "Safety Considerations for Synthetic Sling Surgery".

I know Dr. Blaivas. Who is Dr. Purohit?

A. I don't know. It's a team of urologists and fellows working with Dr. Blaivas.

Q. Okay. Did you consult with Dr. Blaivas on the content of this article?

A. Well, we wrote it together.

Q. And that's my point. Did you work with this whole team in writing the article?

A. Yeah. We were changing, everybody was contributing. It was changed several times, redacted and...

Q. Did you work with any individual specifically, or did you write your own piece and just look after your own section of the article?

A. Oh, it's a joint effort. I mean, the manuscript consult, everybody contributes, puts one piece there, puts one piece there.

It's been changed and then editorial office changes and then we change back and then so forth. By the end of the day each single word may be coming from a different person.

Q. How many drafts did this Exhibit 5

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go through?

A. Five, six.

Q. Do you still have those drafts?

MR. ORENT: Objection.

THE WITNESS: Yes, I do. But I mean this is more of a delicate issue because there are many authors involved and there is research produced information, and it's a work in progress.

What became public is what we see right in front of us. What we decided to be correct to be exposed to the public.

BY MR. THOMAS:

Q. Other than the journal itself, was anybody else involved in the preparation of Exhibit 5?

A. What do you mean?

Q. Did you have any contribution from any other source other than the authors that were listed in the preparation of the article?

A. Everybody listed as authors, everybody who contributed is here. Well, editorial office was working with it also.

Q. And who did you work with at the editorial office?

A. I don't remember now.

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Q. Okay.
A. I mean, they send their paper, they said, okay, this revision needs to be reviewed, please check this, please check that, they suggest some changes, mainly just style. Very strict regarding style.
Q. You said something earlier today, I want to make sure I understand. In this document, there is reference to work that you have done on different meshes in the medical-legal setting.
I thought I understood you to say that you didn't use the slides that were provided to you by Dr. Kreutzer, but that you cut new slides from existing blocks and conducted your analysis on those new slides; is that correct?
A. For some cases, I received only slides, stained and unstained. For some cases I received blocks. As far as I remember, it's been long time.
So I could either use unstained slides which came together with stained slides, or I could ask my lab to do recuts from the blocks which were made before me.
Q. All right. So, your best

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recollection it was a mixture of previously existing slides or recuts from this mesh that you had obtained from Dr. Kreutzer, correct?
A. Yes.
Q. Is the same thing true with your other mesh specimens that were involved in medical-legal field, that on some occasions you'd use existing slides and some occasions you'd use recuts or you'd have recuts made of existing blocks?
A. That's correct. Depends on situation.
Q. I assume you stand by all the findings in this report, correct?
A. It's not findings; this report is a review. So it's more based on the other papers.
Q. Okay?
A. The only thing which was produced in this paper from us personally was figures.
Q. Let's go to one of those figures on page 4.
A. You mean the table?
Q. Table two on page 4?
A. Yes.
Q. And this review paper, in

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reporting longer-term complications, reports pain greater than six weeks for either retropubic or transobturator tape slings at 3.5 percent, correct?
A. Which line?
Q. Third from the bottom, longer-term complications. Do you see it, for refractory pain greater than six weeks?
A. So the incidence range is from 4.1 to 30 percent.
Q. The complications percentage of patients that report refractory pain greater than six weeks is 3.5 percent, correct?
A. What I see is 4.1 to 30 percent.
Q. Well --
A. Third line from the bottom.
Q. I understand that's the mean and the range, correct?
A. Yes.
Q. 4.1?
A. Sorry, 4.1 is mean. Yes, you're correct. I need my glasses.
So this is -- the range is from 0 to 30 percent.
Q. But the average -- excuse me -- the percentage of patients at 7,084 that report

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pain greater than six weeks, is 247 or 3.5 percent, correct? Is that right?
A. Yes and no. So this is a review of previously published studies. So the quality of the studies is different, methodology is different. But when you check them, the pain over six weeks is reporting anywhere from 0 to 30 percent.
Q. Okay.
A. With a mean, or average 4.1 percent.
Q. But these numbers are correct, aren't they?
A. Well, from what we extracted at that stage from the papers, that's what we have.
Q. Okay. You went out and tried to obtain complication rates for retropubic or TOT slings, didn't you?
A. Yes. The whole paper is just for slings.
Q. And as a part of looking at long-term pain which is greater than six weeks, you looked at 7,084 patients, correct?
A. No, we didn't. The papers in combination.
Q. I understand. But you gathered

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papers that looked at over 7,000 patients?
MR. ORENT: Objection.
THE WITNESS: That's what it says there, yes.
BY MR. THOMAS:
Q. And in gathering the papers, who was in charge of picking which studies you looked at?
A. That part -- it's not a study; it is a review.
Q. I apologize.
A. That part of the review was done mainly by urologist.
Q. Do you know who that was?
A. It's a team working with Dr. Blaivas.
Q. So the urologist, the clinicians, are the people who are responsible for identifying the studies to identify the complication rates?
A. That's correct.
Q. And through their best efforts, they identified a percentage of patients that have pain more than six weeks at 3.5 percent, correct?
A. That was an estimate of a minimal, a minimum number. So this is the bottom line. So

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it's minimum of 3.5 percent of the patients will develop chronic pain.
Q. Okay.
A. Which is -- probably doesn't say right away, but that was the minimum. It wasn't that we were implying that it's a true number.
Q. Do you know how many, for how many of those 3.5 percent that the pain was ultimately resolved?
A. Again, 3.5 percent was minimum number.
Q. I understand. But for some of those people they were cured of the chronic pain, weren't they?
MR. ORENT: Objection.
THE WITNESS: After mesh removal?
BY MR. THOMAS:
Q. Or for whatever treatment?
MR. ORENT: Objection.
BY MR. THOMAS:
Q. Do you know that?
A. No, I don't know. I don't think it was in the published literature.
Q. That's fine. Do you know whether the urologist group who were looking at the mesh

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complications looked to see how many people had their pain resolved by surgery or some other treatment?
A. Those papers are reviews. Most of them didn't provide that information. They just provided numbers for complications.
Q. Did you do a literature search yourself to determine the extent to which long-term complications of chronic pain were resolved by surgery or other treatment?
A. Not to answer that specific question. Again, I mean, I only can read what is published. Because studies don't concentrate, don't focus on this question; I cannot get an answer.
Q. Well, this was your group's best effort at presenting, in a reviewed paper, the rate of complications for long-term pain, correct?
MR. ORENT: Objection.
THE WITNESS: Yes, you're correct.
BY MR. THOMAS:
Q. Thank you.
A. But the question is that if I made an effort to look for something which is barely ever published; that's why I answered that it's

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specifically to that question, would be difficult to do.
-- RECESS AT 4:08 --
-- UPON RESUMING AT 4:15 --
BY MR. THOMAS:
Q. Doctor, let's go back to Exhibit No. 5, page 5. I asked you about the wrong chart. I asked you about the chart on page 4.
The chart on page 4 does retropubic and obturator slings. The one on page 5 is limited to retropubic slings; do you see at the top?
A. Yes.
Q. And retropubic slings are what TVT slings are, correct?
A. Yes.
Q. And the long-term refractory pain greater than six weeks reported by your group is 1.8 percent, correct?
A. Yes, but it's not reported by our group.
Q. Collected by your group?
A. Collected from other papers by our group, yes.
Q. And as a part of that, the group looked at studies reporting on about 2,328

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patients, correct?
A. Yes.
Q. Okay. For the slide on page 82, about the -- 83, I'm sorry. About the image of the TVT mesh fibers immediately after surgery removal?
A. Yes.
Q. Did you submit any histology to the journal for publication?
A. For this case?
Q. For the journal. For --
A. Which one?
Q. In one of the studies you have the image of that --
A. It's --
Q. Is it the other journal?
A. Yes, this one.
Q. I'll come back to that.
A. You mean histology of that specific case?
Q. Yes.
A. No.
Q. Have you shared the histology of that specific slide with anybody period?
MR. ORENT: Objection.
THE WITNESS: No.

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BY MR. THOMAS:
Q. So you're the only one that's ever looked at it?
A. Pardon?
Q. You're the only one that's ever looked at it?
A. Yes. I don't think I have pictures, I didn't take pictures.
Q. Okay. Why not?
A. What for?
Q. Okay.
EXHIBIT NO. 6: Article entitled, "Degradation of Polypropylene in Vivo: A Microscopic Analysis of Mesh Explanted from Patients."
BY MR. THOMAS:
Q. Let me show you what's been marked as deposition Exhibit No. 6.
Deposition Exhibit No. 6 is an article entitled, "Degradation of Polypropylene in Vivo: A Microscopic Analysis of Mesh Explanted from Patients". That was just recently released, correct?
A. That is correct.
Q. And you worked with Dr. Guelcher

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and Dr. Bendavid on this?
A. Yes.
Q. Did you receive any funding for your work in Exhibit 6?
A. No.
Q. Did Dr. Guelcher or Dr. Bendavid receive any funding for their work on Exhibit 6?
A. No. The work actually was done mainly by me. Dr. Guelcher and Dr. Bendavid just contributed to the drafting of the manuscript.
Q. What did Dr. Guelcher contribute to the manuscript?
A. The drafting of the manuscript, we discussed mechanism of degradation, mechanically how it happens, oxidation and other aspects.
Q. Do you view Dr. Guelcher as authoritative on the issue of oxidative degeneration -- excuse me.
Do you view Dr. Guelcher as authoritative in the area of oxidative degradation of polypropylene?
A. He's a bio engineer. He works in the area.
Q. How do you feel about him? Do you view him as authoritative in the field?

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MR. ORENT: Objection.
THE WITNESS: I'm not sure if I can answer that question.
BY MR. THOMAS:
Q. Okay?
A. He's a specialist who works in the area and works in the field.
Q. At any time, have you relied upon Dr. Guelcher to tell you, chemically, how polypropylene oxidizes?
A. No. In fact, it wasn't my purpose to answer the question how it oxidizes. It only describes that it does oxidize.
Q. So what role did Dr. Guelcher play in the preparation of Exhibit 6?
A. Drafting of the manuscript, mainly the discussion part. He also suggested at one point when we started working on this, doing a myeloperoxidase stain. Again, in relation to oxidative degradation.
Q. What role did Dr. Bendavid have in this study?
A. Well, he actually brought me to this mesh field and he supplied, or some samples came from Shouldice Hospital, where he worked. And

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he also helped drafting the manuscript.
Q. In terms of the data gathering and the conclusions contained herein, is this basically your work?
A. For the most part.
Q. And I hate to ask you again, but what data gathering or conclusions did Dr. Guelcher or Dr. Bendavid provide?
A. Dr. Guelcher didn't gather any data. As you can read the manuscript or paper, it's all histology.
Q. Okay?
A. So I've been collecting data and analyzing the samples.
But Dr. Bendavid contributed with idea of degradation and contributing some samples, hernia samples, and Dr. Guelcher contributed in drafting the manuscript and also suggesting myeloperoxidase stain and suggesting what is the mechanism of degradation.
But the histology itself, data collection and analysis, was done by me.
Q. As part of the preparation of this paper, did you and your coauthors discuss intentionally oxidizing polypropylene to see if it

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would hold stain?
A. No. This paper was started, or most of the data was collected even before I learned about this simulation model. So it wasn't a part.
Q. Did you ever discuss with Dr. Guelcher different ways to intentionally oxidize polypropylene?
A. Later on. I mean, the manuscript was mainly written already and then we started discussing plans for the future. And then that's how I used the paper he suggested as a recipe for simulation.
Q. Okay. So Dr. Guelcher suggested to you the paper that you used for the simulation?
A. I think so.
Q. Okay?
A. Maybe I saw it before, but he pointed that, that's the recipe he was using as well.
Q. Got it. Is Dr. Guelcher involved in your experimental work on the samples that you're now storing?
A. No. I mean, I had my own samples. His contribution to this work is that I ask him

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what he's using, or I don't remember exactly how the conversation started, and he said that he's using recipe from that specific paper.
Q. I see.
A. And I used it. We didn't have exchange of the samples, or testing of each other's samples.
Q. So you have never analyzed the samples that he tested?
A. No, never seen those.
Q. And you know that he's exposed samples to five and six weeks' worth of exposure?
A. I do know that.
Q. Okay.
A. I do know that.
Q. Have you requested to look at those or test those or analyze those in any form?
A. There was a discussion. I don't know if I said that I don't want to do it because I have my own and I believe it needs to be a year.
Or maybe they used all their samples for SEM, and they didn't have anything left. But at that time the decision was to wait for my samples to become mature.
Q. Okay. Did you submit this article

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to multiple journals?
A. There was submission to at least two journals and the answer was really quick, next day. They said no, it's not in our scope. And I was aiming at really high impact like Nature, so...
Q. Nature turned it down?
A. (Witness nods).
Q. Okay.
A. Are you surprised?
Q. And so is the Journal of Biomedical Materials the only other journal that reviewed it?
MR. ORENT: Objection.
THE WITNESS: Yeah, this is my usual approach. For all my papers I start really high impact journal, hope for the best, and then go from there.
BY MR. THOMAS:
Q. Now, was there a peer-review process of this article?
A. Yes. They ask for revisions, I did revisions, then we drafted it.
Q. How many drafts did you have of Exhibit 6?
A. We had one revision, one large

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revision. Part of the manuscript removed tables.
MR. ORENT: I object to this whole line of questioning. It's outside of the scope of the expert testimony, and moreover I think there's a public policy interest in maintaining the integrity of the editorial board process of the journals.
BY MR. THOMAS:
Q. Do you still have your first draft?
MR. ORENT: Objection.
THE WITNESS: I can't answer that.
BY MR. THOMAS:
Q. You can't?
A. (Nods).
Q. Why?
A. It goes to the issues Mr. Orent just mentioned.
Q. Okay. So have you maintained a file on the preparation, the data you gathered, the submission process and the peer-review process for Exhibit 6?
A. Did I?
Q. Yes.
MR. ORENT: Objection.
THE WITNESS: Yes, I did.

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BY MR. THOMAS:
Q. I just ask you to maintain that file and either I'll get it or I won't. Just don't do anything to it; that's all I ask.
Just so I can short cut this. Is it fair to say you're not going to answer any more questions about the generation, drafting, peer review, submission and publication of the article?
A. It was a standard process. There was nothing unusual about it.
Q. But in terms of the details of it you're not going to answer any questions about that?
A. No. I can tell that you there was nothing unusual.
Q. I understand. If you'll turn to page 2, Table 1 is the sample and patient data?
A. Yes.
Q. And under "Slings", it says that you have 28 TVT or TVT-Os; do you see that?
A. That is correct.
Q. Do you know the breakdown between TVT and TVT-O?
A. No.
Q. Okay. Do you know whether any of

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them are machine cut or laser cut?
A. No.
Q. You have four Prolift products; do you see that?
A. Yes, I do.
Q. And then a number of hernia mesh cases, correct?
A. That is correct.
Q. Of the 69 slings that you analyzed, how many were medical-legal cases?
A. The breakdown was about 70 percent. I cannot tell you exact number. But roughly, it's for the whole set was 70 percent medical-legal and 30 percent hospital cases.
And not necessarily St. Michael's. They were coming from different hospitals.
Q. Okay. Is it fair to say if they're undetermined that they're not medical-legal cases?
A. At least 70 percent were medical-legal.
Q. I understand that, but I'm trying to break it down further to find out which ones were medical-legal and which ones were not.
And you have 45 hernia cases that you

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identify as undetermined. I'm making an assumption that because they're undetermined hernia cases that they're probably not medical-legal cases; is that a fair assumption?
A. Some of them are medical-legal.
Q. What percentage of the undetermined hernia cases were medical-legal; do you know?
A. The undetermined are probably all non-medical-legal. I don't think medical-legal is undetermined.
Q. That was my point?
A. Yes.
Q. So when we're making the calculation of the 70 percent, is it safe for us to exclude -- or strike that.
Is it safe for us to include the 45 undetermined hernia cases in the 30 percent of the non-medical-legal cases?
A. Yes, we can do that right away. Those would be non-medical-legal cases.
Q. Okay.
A. There could be some potentially medical-legal cases when I receive a specimen but I have not received a history. They say, hold on to

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this -- may be medical-legal case later on.
Q. Okay?
A. So it's not hard number.
Q. Right.
A. But it's a ballpark.
Q. For the Ethicon TVT, TVT-O of those 28 how many of them are medical-legal?
A. At least 80 percent.
Q. Perhaps more?
A. Possibly more.
Q. And included within the 28 Ethicon TVT and TVT-O are the cases that you received from Dr. Kreutzer, correct?
A. Yes. Most of St. Michael's cases, when I had a record, were actually TVT. So I don't know for whatever reason most of those excised at St. Michael's were TVT.
Q. Okay. And in addition, you had new TVT and TVT-O cases since Dr. Kreutzer, and those would be included in this article as well?
A. Yes.
Q. So, for example, the Edwards case would probably be in this?
A. Yes, it would be in there. I received the Edwards case before I received

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specimen from Dr. Kreutzer.
Q. Okay. Interesting.
On page 3 of this study, you talk about measuring the degradation layer's thickness?
A. Yes.
Q. And you say a set of 23 mid-urethral slings was the largest uniform group that fulfilled your criteria. Is that the slings that you got from Dr. Kreutzer?
A. Most of them came in that set of samples.
Q. All right. Tell me how you physically measure the thickness of the stained layer with the eyepiece micrometer?
A. I would find fibers which are cut as perpendicular as possible and measure bark thickness on at least two occasions.
And then measure -- I try to find another fiber, measure again, and then take median number, the most frequent I'm getting.
Q. Do you have the data that you collected on those measurements?
A. Yes, I do.
Q. Okay.
A. I mean, you have it on the --

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Q. Is it on the thumb drive?
A. It's on the thumb drive. And you saw it before at various depositions.
Q. Thank you. I don't want to redo that.
And when you do the eyepiece micrometer and you measure, to what level can you measure?
A. Initially, I had one micrometer. It was graded only to one micrometer. Now, I have little bit better so I can measure up to half a micrometer.
Q. When you were doing this study, were you measuring at one micrometer?
A. I was rounding to one micrometer; it was an older eyepiece.
Q. So the data in the study, you're rounding your findings to the closest micrometer?
A. Yes. To the full number.
Q. Did you round up always?
MR. ORENT: Objection.
THE WITNESS: No, it depends. If it's less than a half of the next gradation, it would go to the lower, but that's the usual rule for --
BY MR. THOMAS:
Q. Okay, that's fine. And then when

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you had two together -- so you had a total of four measurements?
A. I would aim at four measurements at least.
Q. And each one of those would go through some rounding process?
A. Yeah, I mean, the accuracy of measurement was within half a micrometer plus or minus.
Q. Okay. Now --
A. But it would be random, up and down, up and down, so they would constantly change.
Q. Now, in some places in images we looked at today, we didn't find any bark, correct?
MR. ORENT: Objection.
THE WITNESS: This is not correct. We could not see it in the images. I can tell you that in some specimens I did not see bark.
BY MR. THOMAS:
Q. How do you report that?
A. I report that I don't see it. I have cases when I reported that I don't see a bark.
Q. And you reported here that you had two specimens where the degradation layer was not visible where a hernia mesh and a sling were

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removed at three and ten months.

Are those the only two times you haven't been able to see a bark?

A. At that time, the only two. Since then I've seen a couple of more cases where I couldn't identify bark.

Q. Any of those medical-legal cases?

A. No, I think it was all hernia meshes, not medical-legal cases.

Q. Do you have those slides available?

MR. ORENT: Objection.

THE WITNESS: Yes, I do, but they are of patients.

BY MR. THOMAS:

Q. You can't produce those to me if I asked you for them?

A. I can't produce them.

Q. Did the slides where there was no degradation bark, if you will, present contain inflammation?

A. Yes, they did.

Q. Were they removed because of pain?

A. Yes. I think one of them was removed for erosion with pain. The other one, the

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hernia mesh, was removed just for pain.

Q. On page 6 of the study, you describe that you use transmission electron microscopy --

A. That's correct.

Q. -- to study the ultra structural organization of the degraded layer in cross-sections?

A. That's correct.

Q. Did you use the TEM to study any TVT device?

A. One. It was one Ethicon device, TVT or Prolift, I don't remember. I think it was a TVT.

Q. Have you produced that work to us before?

A. It's a St. Michael's Hospital patient.

Q. Okay. So, is it fair to understand that the only transmission electron microscopy analysis that you've done on an Ethicon mesh is the St. Michael's patient that you can't produce to us?

A. Well, it was a part of research. So if it was included in images, it was included as

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part of research project.

Q. Well, have you produced that to us before?

A. I don't know.

Q. Okay. But just to make sure I got a clean answer. In all the work that you've done on all the Ethicon meshes, the only Ethicon mesh that you've analyzed by transmission electron microscopy is a mesh of a St. Michael's patient that's either a TVT or a Prolift, you don't know which?

A. Now I'm not sure if it was St. Michael's or it was a medical-legal case. I don't remember now.

Q. Okay?

A. I would have to check, but if it was, it was the only case. I could do only one case of Ethicon mesh by transmission electron microscopy.

Q. And why have you not conducted transmission electron microscopy on other meshes?

A. There was no need. It is a really cumbersome, difficult and --

Q. Does St. Michael's have that kind of equipment?

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A. Yes, we do. Otherwise, I wouldn't be able to do it. It's really expensive to do it somewhere outside.

Q. Did you have to pay St. Michael's to do this?

A. No, it's just part of our academic work.

Q. Are you able to do this yourself or does somebody have to do it for you?

A. I'm trained to do transmission electron microscopy. I mean, technicians prepare slides. It's usual, the same as for histology. But I do examination myself.

Most of the transmission electron microscopy samples are with hernia meshes.

Q. Page 10 there is a discussion of the clinical significance of polypropylene degradation?

MR. ORENT: Are we going back to the report or saying on the study?

MR. THOMAS: I'm on the study, sorry.

THE WITNESS: Yes.

BY MR. THOMAS:

Q. Page 10 on Exhibit 6, "Clinical Significance of Polypropylene Degradation".

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Who drafted this section?
A. Mostly me, partially my coauthors.
Q. Dr. Bendavid?
A. Yes. And well, mostly Dr. Bendavid. I mean, I drafted most of it, but I was getting some corrections or changes, and the changes were coming mostly from Dr. Bendavid.
Q. Exhibits 5 and 6, you stand by the findings stated in each of those articles?
A. Yes, I am.
Q. Do you have depositions scheduled in the next month?
A. I'm not sure if I can disclose that.
Q. Do you have trial responsibilities in the next month?
A. Pardon?
Q. Do you have any trial responsibilities in the next month?
A. No, I don't think so.
Q. Your next trial is a December trial with Ethicon?
A. I'm not sure if I can disclose that either.
Q. Are you choosing not to?

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A. There might be more and earlier, I don't want to disclose that. I'm not sure if I can, if I legally can disclose it.
I mean, if it's not for Ethicon cases. For Ethicon I would disclose, but if it's not then I cannot disclose.
MR. THOMAS: Counsel, there's no legal prohibition for him saying it?
MR. ORENT: You can answer.
THE WITNESS: They said that --
MR. ORENT: Wait, hold on. They said is not an answer. So any communications that you've had are covered by a privilege. So what he's asking specifically are, if anything is firm in terms of a date that you know of, so --
BY MR. THOMAS:
Q. For depositions or trial?
MR. ORENT: For depositions or trial, not any communications about we might do this or might do that. But anything firm that you know you have a date set for.
THE WITNESS: Then everything is changing. I have a set date one deposition. But the rest is still in the air.

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BY MR. THOMAS:
Q. Do you have any set dates for any trials between now and the Ethicon trial?
A. No. Again, nothing set firmly.
Q. Okay.
MR. ORENT: Just a sec. In addition to that, I think in the Cantrell matter I've been working with Kelly Crawford to schedule, I would imagine that would be within the next month. That's an Ethicon case, obviously.
MR. THOMAS: Yes, I know about that. Hang on. Getting close to the end.
-- OFF THE RECORD DISCUSSION --
BY MR. THOMAS:
Q. Doctor, I'm told that the information supplied to us concerning the eyepiece micrometer measurements of the bark layers is expressed in a single value as opposed to the four individual measurements?
A. No, it's a median, I told you that, then I pick median value out of four.
Q. Okay.
A. It is described in the paper. So the volume which goes for analysis is a median one, which is more frequent.

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Q. Do you have the four measurements that you made or did you just pick the -- do you have that as a part of your data set?
A. I just measure them and right there I know how frequent is this measurement or that. So I don't have to put in the paper.
Q. Did you write down or keep a copy of the four individual measurements that you made of the --
A. No, no. The methodology is check four spots. I see three, four, four, four, then four is the winner, so then four goes in the record.
Q. Did you produce your bills today for the time that you spent in this case?
A. In this case?
Q. In this case?
A. Oh, in this. I had billing done for the -- for the report, it's in the folder.
Q. Do you recall how much time and money you've spent on preparing the report in this case, Exhibit 3 and 4?
A. No, I don't.
Q. The invoice that you produced to us on a thumb drive suggests that you have a

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balance, professional services August 14th, August 24th for a total of $8,550 --
A. Sounds right.
Q. -- is that right?
Doctor, I don't see -- I see general part text revision; what does that mean?
A. Revision of the general part.
Q. General party report?
A. Yes.
Q. This report is the first time that you reviewed any Ethicon documents or Ethicon depositions, true?
A. No, there was another case.
Q. I didn't see it in any of your reports before where you reviewed Ethicon depositions and Ethicon documents?
MR. ORENT: One moment.
BY MR. THOMAS:
Q. The only other case it could be would be the Bellew case?
MR. ORENT: The doctor has not testified previously about these issues. I don't know whether or not there has been another report on another matter disclosed.
It may very well be that there is

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something that's still work product and not been disclosed. So I don't want to get into the details of that other potential matter.
BY MR. THOMAS:
Q. Let me just ask it this way: The bills that you've submitted to counsel in this matter do not reflect any charges for time that you've spent reviewing Ethicon documents or depositions, correct?
A. Partially, they do. I reviewed some of that again; it's been drafted earlier.
MR. ORENT: Counsel, just to speed this area up to the extent that it's not clear on the bills, I think what we can do is we can supplement by letter.
MR. THOMAS: That would be fine. I'm not interested in getting anybody. I just want --
MR. ORENT: I think what we'll do is we can figure out the amount of time.
MR. THOMAS: I just want to make sure you get paid for your time. You have to send your bills and get paid.
Okay, that's all the questions I have, Doctor. Thank you.
THE WITNESS: Thank you.

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MR. ORENT: Why don't we take two minutes. I'll going to have probably about ten minutes worth of questions.
-- RECESS TAKEN AT 4:52 --
-- UPON RESUMING AT 4:55 --
CROSS-EXAMINATION BY MR. ORENT:
Q. Good afternoon, Doctor.
A. Good afternoon.
Q. Earlier today you were asked a number of questions about each of the photomicrographs that we looked at, and one of the predicate questions that you were asked for each one was whether or not it was a TVT or a TVT-O; do you recall being asked that series of questions?
A. Yes, I do.
Q. For purposes of your work does it make any difference whether or not the product is the TVT or TVT-O in terms of your findings as reported here?
A. No, it's the same sling, the same mesh. The only difference is how it's placed and the other components which come in the kit.
Q. So if I understand your testimony, is it your testimony that the TVT and the TVT-O -- the actual mesh device is the exact same?

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A. Exactly the same.
Q. Okay. And so in terms of the pathological findings that you make, as reported in your report and your supplement, is there a -- is there any reason for making a distinction between the two devices?
MR. THOMAS: Object to the form of the question.
THE WITNESS: No. The only difference is there can be more frequent occurrences of striated muscle in the TVT-O samples than in TVT, but it can be seen in both.
BY MR. ORENT:
Q. And is that because of the implantation route?
A. That's correct.
Q. And both devices are made of Prolene mesh; is that correct?
A. That is correct.
Q. Now every one of the photomicrographs that appear in Exhibits 1 and 2 to today's deposition, that is your report and supplemental report, did every one of those photomicrographs appear either from prior expert reports in Ethicon litigation, in the specific

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pathology of the consolidated plaintiffs, or in peer-reviewed medical literature written by you?

A. That's correct. These are the three sources.

Q. And you've been asked questions today about identifying various -- what you called additional TVT cases in your report; do you recall those questions?

A. Yes, I do.

Q. Did you produce photomicrographs of the additional TVT cases in the course of other reports you've provided in TVT cases?

A. Yes, I did.

Q. Now, with regard to the opinions that you express in your expert report in this case, and your supplement, do you use the same methodology that you have previously used when you testified in the western district -- excuse me, in the southern district of West Virginia?

A. Yes, exactly the same methodology.

Q. And is your -- the materials and your methodology that you utilized in this report the same methodology that you've used in other courts where you have been allowed to testify at trial?

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A. That's correct.

Q. Did you use any different techniques in this report?

A. No.

Q. Okay. Now, the opinions that you testified to in this report, and in the supplement, are they identical to the opinions that you've previously provided in trial in matters before the southern district of West Virginia?

A. Yes.

MR. THOMAS: Object to form.

THE WITNESS: That is correct. The same opinions.

BY MR. ORENT:

Q. Are they, the opinions that you express in your expert report and in the supplement, are they also identical to opinions that you have provided in other courts during trials throughout the country?

MR. THOMAS: Object to form.

THE WITNESS: That is correct.

BY MR. ORENT:

Q. And throughout the course of your report you provide just a few examples of a variety of failure modes associated with the TVT and TVT-O

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device; is that correct?

MR. THOMAS: Object to form.

THE WITNESS: That is correct.

BY MR. ORENT:

Q. And why is it that you don't list a sample size or rate of error in your report?

A. It's not the purpose. I'm not analyzing statistically frequency or rate of occurrence. I showed the changes which can occur. It's binary assessment; either it can occur or cannot occur. It can occur in one case, it can occur in 100 percent of cases, but it can happen. For a specific patient it either occurs or it doesn't.

Q. In order to show that something can occur, in terms of a failure mode, is there a sample size, a minimum sample size that you have need to show that a failure rate or failure mode can occur?

MR. THOMAS: Object to form.

THE WITNESS: One case is enough. If it can occur in one case, it can occur again.

BY MR. ORENT:

Q. And these concepts of sample size with one being enough to prove capability, is that

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something that's generally accepted in the medical community, in the scientific community?

MR. THOMAS: Object to form.

THE WITNESS: Yes. If you answer the question if it can occur, one case is enough.

BY MR. ORENT:

Q. Same thing with a binary observation; it either occurs or doesn't occur. There's no rate of error associated with that; is that correct?

MR. THOMAS: Object to the form of the question.

THE WITNESS: It's either there or it's not. It's either zero occurrence or 100 percent.

BY MR. ORENT:

Q. When you talk about using large enough sample sizes and large enough rates of error, is that only used when you actually try and extrapolate from a data set to an individual?

MR. THOMAS: Object to the form of the question.

THE WITNESS: That's used to predict specific rates of specific occurrence, and that's used in relation to a cohort of patients and devices. And it's a different question.

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BY MR. ORENT:
Q. Okay. And in terms of the opinions that you provided here in your expert report, do you hold each of those opinions to a reasonable degree of medical and professional certainty?
A. Yes, I do.
Q. And with regard to the various staining techniques that you've utilized, are each one of those staining techniques peer-reviewed in their own right?
MR. THOMAS: Object to the form of the question.
THE WITNESS: That is correct, yes.
BY MR. ORENT:
Q. Has H&E been utilized as a stain and been peer-reviewed as a proper way of looking at tissue for a significant period of time?
A. Over 100 years, or over the course of 100 years.
Q. How about myeloperoxidase, has that been peer-reviewed as use for staining?
MR. THOMAS: Object to the form of the question.
THE WITNESS: We have several decades

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of use.
BY MR. ORENT:
Q. And how about S100?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Same thing. It's been used since late '70s, early '80s.
BY MR. ORENT:
Q. What about the use of polarizing light, is that something that's peer-reviewed and accepted in the identification of crystalline substances?
A. It's been described for histology use from 1920s, and even I saw it's been used in Ethicon studies as well. Ethicon scientists were using polarized light as well. Well, let me rephrase that. Who came to the same conclusions I came.
Q. And with regard to the medical peer-reviewed literature on mesh and mesh complications, in fact, there's a group out of the University of Michigan that published utilizing some of the same techniques that you've described in your report; is that correct?
MR. THOMAS: Object to the form of the

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question.
THE WITNESS: Yes.
BY MR. ORENT:
Q. Now, with regard to the work that you've done here, none of these opinions are new; is that right?
MR. THOMAS: Object to the form of the question.
THE WITNESS: That is correct.
BY MR. ORENT:
Q. And in terms of the material that you've produced on disk. Having provided to counsel today, did you produce all non-confidential materials that you could provide?
A. Yes. I selected that I could safely release.
Q. You were also asked a number of questions about the peer review and peer-review process; do you recall those questions?
A. Yes, I do.
Q. As an academic, do you have concerns about maintaining the integrity of the peer-review process?
A. Could you repeat the question.
Q. Sure. As an academic, as an

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author and a researcher, are there important reasons why the confidentiality of the peer-review process needs to be maintained?
A. Yes. I mean, especially when there is an involvement of a manufacturer, because I mean, this is major concern.
Most publications -- journals, they require, the first thing they need to have submitted, has it been funded by industry, by manufacturers. So it's a major concern to try to be independent from manufacturers.
MR. ORENT: All right, Doctor, thank you very much. I have no further questions.
MR. THOMAS: Thank you, Doctor, for your time.

-- Whereupon the deposition concluded at 5:05 p.m.

REPORTER'S CERTIFICATE

I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 14th day of September, 2015.

_____

PER: JUDITH CAPUTO, RPR, CSR, CRR

CERTIFICATE OF REPORTER

CANADA)
PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

_____

Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking
Oaths in the Province of Ontario

INSTRUCTIONS TO WITNESS

Read your deposition over carefully. It is your right to read your deposition and make changes in form or substance. You should assign a reason in the appropriate column on the erratum sheet for any change made.

After making any changes in form or substance, and which have been noted on the following erratum sheet, along with the reason for any change, sign your name on the erratum sheet and date it.

Then sign your deposition at the end of Your testimony in the space provided. You are signing it subject to the changes you have made in the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature.

Return the original erratum sheet promptly. Court rules require filing within 30 days after you receive the deposition.

* * ERRATA SHEET * *

NAME OF CASE: TERRESKI MULLINS, ET AL. V. ETHICON, INC., ET AL.
DATE OF DEPOSITION: SEPTEMBER 14th, 2015
NAME OF WITNESS: VLADIMIR IAKOVLEV

PAGE	LINE	FROM	TO

_____

VLADIMIR IAKOVLEV

PROVINCE OF ONTARIO)
TORONTO REGION)

I, the undersigned, declare under penalty of perjury that I have read the foregoing transcript, and I have made any corrections, additions or deletions that I was desirous of making;

That the foregoing is a true and correct transcript of my testimony contained therein.

_____

VLADIMIR IAKOVLEV, M.D.

Subscribed and sworn to before me this ____ Day of _____, 2015 at _____, _____

(City) (Province)

_____

(Notary Public)

My Commission Expires: _____